



**Acceptance and Commitment Therapy self-help intervention for depression in
haemodialysis patients: A feasibility randomised controlled trial**

Short title: Self-help for haemodialysis patients with depression

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A thesis submitted in part fulfilment of the requirements of the University of Lincoln
for the degree of Doctor of Clinical Psychology

2016

Thesis Abstract

Objective: People with end-stage renal disease (ESRD) experience high rates of depression and this is associated with poorer health-related outcomes. Acceptance and Commitment Therapy (ACT) has shown promising results in a number of long-term conditions and has been translated into a variety of self-help formats. We aimed to determine the feasibility of a trial examining telephone-supported self-help based on ACT for individuals with ESRD who experience depression. A brief and extended account of the research is provided. This is preceded by a systematic literature review examining whether ACT interventions can improve quality of life in long-term physical conditions (see section for more information).

Design: A feasibility randomised controlled trial comparing telephone-supported ACT self-help with treatment as usual.

Methods: Participants were recruited from four outpatient haemodialysis units across Nottinghamshire, UK. The Patient Health Questionnaire (PHQ-9), EuroQol (EQ-5D-5L) health-related quality of life measure, Acceptance and Action Questionnaire II (AAQ-II) and Valued Living Questionnaire (VLQ) were completed at baseline and 2- and 4-months post-randomisation. Participants in the intervention arm were asked to complete an ACT self-help manual over six weeks with weekly telephone support. Following completion of the trial, six participants were interviewed to examine the acceptability of the trial procedure and intervention. Interview data was analysed using framework analysis.

Results: In total, 99 (36.87%) of 276 screening questionnaires were returned. Of these, 30 (30.3%) met the cut-off for depression on the PHQ-9 with nine enrolling in the trial. AAQ-II scores of screened participants were positively associated with scores on the PHQ-9 and GAD-7, indicating a positive relationship between psychological inflexibility and distress. Interview data indicated that the recruitment and randomisation procedure, and assessment methods were acceptable. Only one in four of the participants in the ACT arm of the trial completed all chapters of the book with health problems the main barrier to completion.

Conclusion: Our findings indicate that a definitive trial examining the effectiveness of a telephone-supported ACT self-help intervention would not be feasible. Many aspects of the trial were acceptable to participants, including the main recruitment strategy, randomisation procedure and data collection methods. However, low recruitment numbers and poor adherence to the self-help manual indicate that a full-scale trial would not be viable. Factors

that might account for low recruitment numbers are discussed and personal reflections on the research process are provided.

Acknowledgements

I would like to thank Drs Roshan das Nair and Nima Moghaddam for their guidance and support throughout the training programme and research process. I would also like to thank Dr Emma Coyne and the renal staff teams for their help in conducting this research, and my fellow trainees for their friendship and support. Special thanks to the renal patients who participated in this project. Thanks also to my glorious comrades, Nick Stennings, Tom Wray, Dave Litchfield, Cat Rosser, Dan Doona and Matthew Beechey. Final thanks go to Clare Donnelly for her enduring morale and plentiful sympathy.

Statement of Contribution

Drs Roshan das Nair (RdN) and Nima Moghaddam (NM) provided support in designing the trial, application for ethical approval, data analysis and the writing of this paper. Dr Emma Coyne and staff teams at the dialysis units provided support in screening and recruitment. Barnaby Proctor (BP), Trainee Clinical Psychologist, conducted feasibility interviews.

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Systematic Review

Running head: ACT for long-term physical health conditions

Can Acceptance and Commitment Therapy (ACT) improve quality of life in long-term physical health conditions?

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Abstract

Purpose: Long-term physical health conditions can significantly affect quality of life. With the prevalence of long-term physical health conditions rising, there is an urgent need to identify effective interventions that improve quality of life for those affected. Our aim was to determine the effectiveness of acceptance and commitment therapy (ACT) at improving quality of life in long-term physical health conditions.

Methods: MEDLINE, Embase, PsycINFO, Web of Science and CINAHL were systematically searched along with reference lists and the website of the Association for Contextual Behavioral Science.

Results: Fifteen studies met inclusion criteria (total n=889). Health conditions included chronic pain, tinnitus, epilepsy, ovarian cancer and fibromyalgia. Overall these studies support the use of ACT in a variety of delivery formats for improving quality of life in some long-term conditions.

Conclusions: Preliminary evidence supports the effectiveness of ACT for improving quality of life in cancer, epilepsy and fibromyalgia but not in tinnitus. The findings are mixed for chronic pain. Delivery format (e.g. individual psychotherapy, group psychotherapy or self-help) was not related to the effectiveness of the ACT intervention. Future large scale trials, which address the methodological issues highlighted, are needed before stronger conclusions can be drawn.

Key words: Acceptance and Commitment Therapy, systematic review, methodological quality, evidence-base.

Impact and Implications Statement

What is already known on this subject?

- Studies have demonstrated the efficacy of Acceptance and Commitment Therapy (ACT) at improving outcomes in some chronic conditions however quality of life is often overlooked.
- Acceptance and mindfulness-based approaches (including ACT) are effective at improving quality of life in chronic pain.

What does this study add?

- Preliminary evidence supports the efficacy of ACT for improving quality of life in cancer, epilepsy and fibromyalgia.
- ACT not currently supported for improving quality of life in tinnitus, with mixed findings in chronic pain.
- Methodological issues need to be addressed before stronger conclusions can be drawn.

Background

A long-term condition is defined as “a condition that cannot, at present, be cured but is controlled by medication and/or other treatments/therapies” (pp. 3, Department of Health, 2012). It is a term used to describe a range of physical, mental and neurological disorders. In England in 2010 there were 15.4 million people experiencing at least one long-term condition with the cumulative cost of care estimated to be 70% of the total National Health Service (NHS) budget (Department of Health, 2010). As the population in England over the age of 65 continues to increase, the number of people with long-term conditions is predicted to grow, estimated to be 18 million by 2025 (Department of Health, 2010).

Long-term conditions can affect all aspects of physical and psychological well-being and are associated with a reduction in quality of life (Department of Health, 2010). The NHS Outcomes Framework 2014 to 2015 identifies enhancing the quality of life for people with long-term conditions as a key priority for improvement in health outcomes (Department of Health, 2013). This highlights the urgent need to evaluate interventions aimed at improving quality of life in individuals with long-term conditions.

Acceptance

Traditional Cognitive Behavioural Therapy (CBT) approaches to long-term conditions emphasise control-based strategies aimed at reducing or controlling symptoms (McCracken & Eccleston, 2005). In recent years, a number of new therapeutic approaches within the CBT family have been advanced, which centre on acceptance-based strategies. One such approach, Acceptance and Commitment Therapy (ACT; Hayes, Strosahl & Wilson, 1999) defines acceptance as the willingness to experience distressing private events (thoughts, emotions, physical symptoms) without making attempts to change their form or frequency. In the ACT model, acceptance is conceptualised in opposition to experiential avoidance: a process wherein individuals engage in increasingly narrow and inflexible patterns of behaviour in order to avoid painful and distressing experiences. According to Hayes et al. (1999), these patterns of experiential avoidance lead to greater disability and diminished quality of life.

Acceptance has been found to be positively related to psychological well-being across a broad spectrum of long-term conditions such as coronary artery disease (Karademas, Tsagaraki & Lambrou, 2009), multiple sclerosis (Harrison, Stuifbergen, Adachi &

Becker, 2004), diabetes (Richardson, Adner & Nordstrom, 2001) and chronic pain (McCracken & Zhao-O'Brien, 2010).

A growing body of research has attempted to examine the effectiveness of ACT at improving outcomes in chronic illness especially chronic pain. ACT is now recommended by the American Psychological Association's (APA) Society of Clinical Psychology as an evidence-based treatment for chronic pain. In a systematic review, Veehof, Oskam, Schreurs and Bohlmeijer (2011) examined the effectiveness of acceptance-based interventions for the treatment of chronic pain. Following a meta-analysis of 14 controlled studies, the authors concluded that acceptance-based interventions are effective at reducing pain and depressive symptoms with small effect sizes ($SMD=0.37$ and 0.32 respectively). A moderate effect was reported on quality of life ($SMD=0.41$), although only six studies included a quality of life outcome measure.

Importantly, of the 22 studies included in the review, only seven involved an ACT intervention. The remaining 15 involved another acceptance-based intervention, namely the mindfulness-based stress reduction program (Kabat-Zinn, 1990). Given that ACT is a unique psychotherapeutic model with its own set of processes and techniques, there is a need to examine its utility independently of other acceptance-based approaches.

A particular point of distinction is that in contrast to other acceptance-based approaches, ACT promotes acceptance as a *means* of bringing about values-based behaviour, rather than as an end in itself. In ACT, acceptance is considered useful to the extent that it can increase behavioural flexibility (i.e. counteract experiential avoidance) and enable action in accordance with personal values and long-held goals – despite the presence of pain or distressing thoughts and feelings. If an ACT intervention is successful in fostering increased acceptance and valued behaviour, we would expect to see this reflected in improved quality of life.

Aims

The present study aims to systematically review the effectiveness of ACT interventions for improving quality of life in adults with long-term physical health conditions.

Methods

Inclusion and exclusion criteria

One reviewer identified potentially eligible studies based on titles and abstracts. Full-text articles were then examined to determine which papers met inclusion criteria. The following criteria were adopted:

Study designs

We considered randomised controlled trials (RCTs) as they are considered the gold standard for evaluating the effectiveness of interventions. Quality, based on methodology, was assessed for included studies. Conference abstracts and other grey literature were excluded along with uncontrolled trials, case studies, reviews and commentaries. Our decision to omit grey and other unpublished literature was based on findings that the methodological quality of such studies is often poorer than those that have been published (Egger, Juni, Bartlett, Hoenstein & Sterne, 2003). Non-English language papers were also excluded.

Participants

Studies were included if their participants experienced one or more long-term *physical* health conditions. Participants did not have to have a formal diagnosis but where diagnosis was not present, researchers needed to have specified how the presence of the condition was determined. Studies where participants were carers of patients with long-term conditions were excluded, unless the intervention was delivered to both the patient and the carer(s) and separate data were available for the analysis of patient outcomes. Studies involving children and adolescents were not included.

Interventions and control groups

Trials were included where there was a comparison between a standardised ACT intervention and a control condition featuring either another type of treatment or no treatment (e.g. waiting list). All ACT interventions were included regardless of the delivery format or length but had to be based upon the core processes of ACT.

Outcome measures

Quality of life was defined as an individual's perceived quality of their physical, psychological, social and existential functioning (Anderson, Aaronson & Wilkin, 1993).

Studies were considered where they included generic quality of life measures and health-related or illness-specific measures.

Search strategy

Five databases were searched using a comprehensive search strategy: MEDLINE (1946 to July 2014), Embase (1980 to July 2014), PsycINFO (1806 to July 2014), Web of Science (1900 to July 2014) and CINAHL (1937 to July 2014). The databases were searched using the following terms: “randomised”, “randomized”, “randomize”, “randomise”, “randomisation”, “randomization”, “randomly”, and “clinical trial” in combination with “acceptance and commitment therapy”, “acceptance & commitment therapy” “acceptance-based” and “acceptance based”. The terms were searched as MeSH subject headings (where available) and key words within titles and abstracts. Forward citation tracking was also used and reference lists of relevant papers were searched.

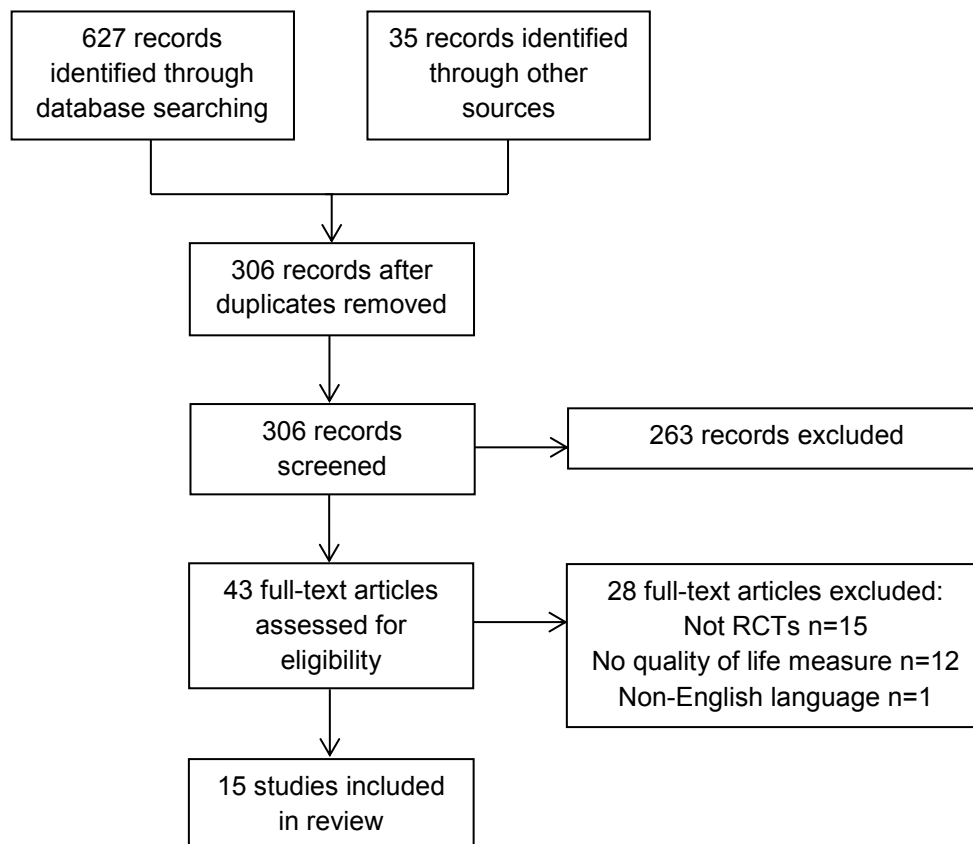
Additional search strategies were also employed. The official website of the Association for Contextual Behavioral Science (ACBS: <https://www.contextualscience.org>) provides a list of publications relevant to ACT including clinical trials of ACT interventions. The “ACT Empirical” section of this list was searched to identify additional trials. Titles and abstracts were reviewed to identify studies for further screening. The ACBS website also provides an electronic mailing list which allows users to contact researchers and clinicians to discuss current conceptual, scientific, and practice developments in ACT. An email outlining the details of the review and requesting relevant papers was sent to the “ACT for Professionals” electronic mailing list. This search strategy was used as an expert consultation to identify additional papers.

Quality assessment

The psychotherapy outcome study methodology rating scale (Öst, 2008) was used to assess the methodological quality of identified studies (see Table 1). The 22-item scale was adapted by Öst to evaluate the general quality of outcome studies and was used in their review of the effectiveness of third wave behavioural therapies (including ACT). Each item is rated as 0 = poor, 1 = fair or 2 = good. Detailed guidance for scoring can be seen in Appendix A. One reviewer evaluated the studies with a proportion checked by a second reviewer. Disagreements between reviewers were resolved through discussion.

Figure 1

Study flow diagram



Results

Overview of included studies

A study flow diagram can be seen in Figure 1 and an overview of included studies can be seen in Table 2. Fifteen studies were identified as eligible for the review, covering chronic pain or whiplash associated disorders (n=8), fibromyalgia (n=2), tinnitus (n=2), drug-refractory epilepsy (n=2) and ovarian cancer (n=1). All included studies adopted an RCT design. The main reasons for excluding full-text articles were that the studies did not use an RCT design (n=15) or that they did not include a measure of quality of life (n=12). One full-text article was excluded because an English language version of the paper was not available. In terms of study location, nearly half were from Sweden (n=14) with the rest from USA (n=3), Spain (n=2), India (n=1) New Zealand (n=1) and South Africa (n=1).

Table 1

Methodological quality of included studies

Item	Alonso et al. 2013	Buhrman et al. 2013	Dahl et al. 2004	Hesser et al. 2012	Johnston et al. 2010	Luciano et al. 2014	Lundgren et al. 2006	Lundgren et al. 2008	Rost et al. 2012	Thorsell et al. 2011	VanBuskirk et al. 2014	Westin et al. 2011	Wetherell et al. 2011	Wicksell et al. 2008	Wicksell et al. 2012
i. Clarity of sample description	1	2	1	1	1	1	1	1	1	1	2	1	2	1	1
ii. Severity/chronicity of the disorder	2	0	0	1	0	1	1	1	2	0	0	1	0	1	2
iii. Representativeness of the sample	0	1	0	1	1	2	1	1	2	2	1	1	1	1	0
iv. Reliability of the diagnosis in question	0	0	0	1	0	1	1	1	1	0	0	1	0	0	0
v. Specificity of outcome measures	2	2	1	1	1	2	1	1	1	1	2	1	2	1	1
vi. Reliability and validity of outcome measures	2	2	1	2	1	2	2	2	1	1	2	2	2	2	2
vii. Use of blind evaluators	0	2	0	2	0	1	0	0	0	2	2	1	2	1	1
viii. Assessor training	0	n/a	0	n/a	0	0	0	0	0	n/a	0	0	0	0	0
ix. Assignment to treatment	1	1	0	2	1	1	1	1	1	1	1	1	1	1	1
x. Design	0	1	0	2	0	2	1	2	0	2	2	2	2	0	0
xi. Power analysis	0	1	0	0	0	2	0	0	0	1	0	1	0	0	0
xii. Assessment points	0	0	1	2	0	1	2	2	0	2	1	2	1	0	1
xiii. Manualised, replicable, specific treatment programs	1	1	1	1	1	1	1	1	0	1	1	1	1	1	1
xiv. Number of therapists	0	1	1	1	0	0	1	1	0	1	1	0	1	2	2
xv. Therapist training/experience	2	0	0	0	0	2	1	1	0	0	0	0	0	1	1
xvi. Checks for treatment adherence	0	1	0	1	2	1	1	1	1	0	1	1	1	0	1
xvii. Checks for therapist competence	0	0	0	1	0	1	1	1	0	0	1	1	1	0	1
xviii. Control of concomitant treatments (e.g. medications)	0	0	1	1	0	1	1	0	0	1	2	2	2	0	1
xix. Handling of attrition	0	1	0	2	1	1	0	0	1	1	0	1	1	1	1
xx. Statistical analyses and presentation of results	2	2	2	2	2	2	2	2	1	2	1	2	2	2	2
xxi. Clinical significance	0	0	0	1	2	0	0	0	0	0	0	2	0	0	0
xxii. Equality of therapy hours (for non-wait-list designs only)	n/a	0	n/a	2	n/a	0	2	2	2	2	2	0	2	n/a	n/a

Note: 0 = poor rating or not enough information given; 1 = fair rating; 2 = good rating; n/a = not applicable.

Sample characteristics

In total, selected studies included 889 participants with sample sizes ranging from 10 to 156. Of the 889 participants, 592 (66.59%) were female and 297 (33.41%) were male. The number of females was skewed by one study which included 150 females and only 6 males (Luciano et al., 2014). Two studies included no males; one involved a sample of ovarian cancer patients (Rost, Wilson, Buchanan, Hildebrandt & Mutch, 2012) and the other chose to exclude males from the sample but gave no reason (Wicksell et al., 2013). The average age of participants across all studies was 49.31 years, ranging from 18 to 91 years.

Treatment and control conditions

A summary of outcomes is presented in Table 3. Various formats were used in the delivery of the ACT intervention including individual psychotherapy (n=4), group psychotherapy (n=5), internet-based self-help (n=2), bibliotherapy with therapist telephone support (n=2) and combined individual and group psychotherapy (n=2). Several different control groups were utilised, including CBT delivered in group (n=2), individual (n=1) and internet-based formats (n=1); moderated online internet forum (n=2); combined group and individual supportive therapy (n=1); tinnitus retraining therapy (n=1); pharmacological treatment (n=1); applied relaxation self-help manual (n=1); yoga (n=1); and medical treatment as usual (TAU; n=1). Over a third of studies (n=6) included a wait-list control condition, two of which also included a third condition featuring another type of treatment, namely pharmacological treatment or internet-delivered CBT, as mentioned above.

Quality of life measures

In almost all included studies, quality of life was a secondary outcome with primary outcomes tending to be related to reductions in psychological distress, increase in activity, reduction in sick leave or medical utilisation, or reduction in self-reported symptoms related to the long-term condition. ACT-specific measures such as the Acceptance and Action Questionnaire II (AAQ-II: Bond et al., 2011) were used in most of the studies. These instruments measure the therapeutic processes underlying the ACT model.

The majority of studies used a general quality of life measure (n=10) with three studies using two general measures. The general measures were the Satisfaction with Life

Table 2

Characteristics of included studies

Author	Country	Target	Mean age	Female	Male	n	Treatment and control conditions
Alonso et al. 2013	Spain	Chronic pain	85.4	8	2	5 5	Group ACT Wait-list
Buhrman et al. 2013	Sweden	Chronic pain	49.1	45	31	38 38	Internet ACT Moderated online forum
Dahl et al. 2004	Sweden	Chronic pain	40	17	2	11 8	Individual ACT + MTAU MTAU
Hesser et al. 2012	Sweden	Tinnitus	48.5	43	56	35 32 32	Internet ACT Internet CBT Moderated online forum
Johnston et al. 2010	New Zealand	Chronic pain	43	14	10	6 8	Self-help ACT Wait-list
Luciano et al. 2014	Spain	Fibromyalgia	48.31	150	6	51 52 53	Group ACT RPT Wait-list
Lundgren et al. 2006	South Africa	Drug-refractory epilepsy	40.68	14	13	14 13	Group + individual ACT Group + individual ST
Lundgren et al. 2008	India	Drug-refractory epilepsy	23.85	6	12	10 8	Group + individual ACT Yoga
Rost et al. 2012	USA	Ovarian cancer	56	47	0	25 22	Individual ACT Individual CBT (TAU)
Thorsell et al. 2011	Sweden	Chronic pain	46	58	32	52 38	Self-help ACT Self-help applied relaxation
VanBuskirk et al. 2014	USA	Chronic pain	56.25	48	39	41 46	Group ACT Group CBT
Westin et al. 2011	Sweden	Tinnitus	50.9	28	32	21 18 21	Individual ACT TRT Wait-list
Wetherell et al. 2011	USA	Chronic pain	54.9	58	56	57 57	Group ACT Group CBT
Wicksell et al. 2008	Sweden	Chronic pain and whiplash	51.65	16	6	11 10	Individual ACT Wait-list
Wicksell et al. 2012	Sweden	Fibromyalgia	45.1	40	0	23 17	Group ACT Wait-list

Note: Individual ACT = individually delivered ACT; Group ACT = group delivered ACT; Group + individual ACT = combined individual and group delivered ACT; Group + individual ST = combined individual and group delivered supportive therapy; Internet ACT = internet-delivered ACT; Internet CBT = internet-delivered CBT; MTAU = medical treatment as usual; RPT = recommended pharmacological treatment; TRT = tinnitus retraining therapy; self-help ACT = ACT bibliotherapy; TAU = treatment as usual.

Scale (SWLS: Diener, Emmons, Larsen & Griffins, 1985; n=6), the Quality of Life Inventory (QOLI: Frisch, Cornell, Villanueva & Retzlaff, 1992; n=4), and the World Health Organization Quality of Life scale (WHOQOL-BREF: WHOQOL Group, 1998; n=2). Several studies adopted a measure of health-related quality of life including the

Medical Outcomes Study 12-Item Short Form Health Survey (SF-12: Ware, Kosinski & Keller, 1994; n=2), the 36-Item Short Form Health Survey (SF-36: Ware & Sherbourne, 1992; n=1), and the EQ-5D visual analogue scales (EQ-5D VAS: EuroQol Group, 1990; n=1).

Two studies used illness-specific measures. The Life Satisfaction Questionnaire (LSQ: Carlsson, Hamrin & Lindquist, 1999) was developed to measure quality of life in women with breast cancer but has also been used with individuals experiencing other chronic physical health conditions. The LSQ was used within the Dahl, Wilson and Nilsson (2004) study to assess quality of life in individuals who experience chronic pain. The Functional Assessment of Cancer Therapy (FACT-G: Cella, 1997) is a cancer-specific measure of quality of life which was used within the Rost et al. (2012) study. An average effect size was calculated for studies where more than one quality of life measure was used.

Chronic pain

In total, eight studies, using a variety of delivery formats, examined ACT for chronic pain. Three studies used a group based format for delivering the ACT intervention although one (VanBuskirk, Roesch, Afari & Wetherell, 2014) was an ancillary of another (Wetherell et al., 2011). As the ancillary study reports no new data relating to quality of life, no further description is provided here. In the parent study, Wetherell et al. (2011) compared ACT with CBT in a randomised sample of 114 individuals with chronic pain. Both the ACT and CBT protocols consisted of eight 90-minute weekly group sessions. There were no significant improvements in mental or physical health-related quality of life as measured by the SF-12, in either the ACT or CBT groups, at post treatment or six-month follow-up. Furthermore, there were no significant differences between the two conditions. When ACT was compared with a baseline TAU period, again, no significant differences were found. The methodological quality of the study was high, particularly in relation to the inclusiveness and size of the sample.

In a cluster-RCT design, Alonso, Lopez, Losada and Gonzalez (2013) randomised two residential care homes to receive group ACT or wait-list control. Individual randomisation was not deemed necessary due to the similarity of the homes. Participants were 10 elderly residents with chronic pain. The ACT group received 10 two-hour group sessions over five weeks. Scores on the SWLS did not significantly improve from pre- to post-treatment for individuals in the ACT condition and no follow-

Table 3

Summary of outcomes of included studies

Author	Target	QOL outcome measure	Time of follow-up	Summary of QOL findings
Alonso et al. 2013	Chronic pain	SWLS	No follow-up	No statistical difference between ACT and wait-list, but small effect favouring ACT ($d = 0.43$)
Buhrman et al. 2013	Chronic pain	QOLI	No follow-up	No statistical difference between ACT and online forum ($d = 0.03$)
Dahl et al. 2004	Chronic pain	LSQ	6 months	No statistical difference between ACT and treatment as usual ($d = 0.26$)
Hesser et al. 2012	Tinnitus	QOLI	12 months (no follow-up data for control)	No statistical difference between ACT and CBT ($d = -0.03$) Small (non-significant) effect favouring ACT vs. online forum ($d = 0.35$)
Johnston et al. 2010	Chronic pain	QOLI SWLS	No follow-up	ACT superior to wait-list (average $d = 0.91$)
Luciano et al. 2014	Fibromyalgia	EQ-5D VAS	6 months	ACT superior to pharmacological treatment ($d = 0.85$) – maintained at follow-up
Lundgren et al. 2006	Drug-refractory epilepsy	WHOQOL-BREF SWLS	12 months	ACT superior to supportive therapy (average $d = 1.05$) – maintained at follow-up
Lundgren et al. 2008	Drug-refractory epilepsy	WHOQOL-BREF SWLS	12 months	ACT superior to yoga (average $d = 0.36$) – maintained at follow-up
Rost et al. 2012	Ovarian cancer	FACT-G	No follow-up	ACT superior to CBT ($d = 1.35$)
Thorsell et al. 2011	Chronic pain	SWLS	12 months	ACT superior to applied relaxation ($d = 3.01$) – maintained at follow-up
VanBuskirk et al. 2014	Chronic pain	SF-12	6 months	Ancillary study – see Wetherell et al. 2011
Westin et al. 2011	Tinnitus	QOLI	18 months (no follow-up for control)	No statistical difference between ACT and tinnitus retraining therapy ($d = 0.08$) or wait-list ($d = 0.12$)
Wetherell et al. 2011	Chronic pain	SF-12	6 months	No statistical difference between ACT and CBT ($d = -0.06$)
Wicksell et al. 2008	Chronic pain and whiplash	SWLS	6 months (no follow-up for control)	ACT superior to wait-list ($d = 1.12$) – maintained at follow-up
Wicksell et al. 2012	Fibromyalgia	SF-36	3-4 months	ACT superior to wait-list for mental health-related QOL ($d = 0.84$) but not physical health-related QOL ($d = 0.19$)

Note: Positive values of effect-size d are in direction favouring ACT over comparator; where a single study used multiple measures of QOL, an average effect-size was computed. EQ-5D VAS = EQ-5D visual analogue scale; FACT-G = Functional Assessment of Cancer Therapy; LSQ = Life Satisfaction Questionnaire; QOL = quality of life; QOLI = Quality of Life Inventory; SF-12 = Medical Outcomes Study 12-Item Short Form Health Survey; SF-36 = Medical Outcomes Study 36-Item Short Form Health Survey; SWLS = Satisfaction with Life Scale; WHOQOL-BREF = World Health Organization Quality of Life.

up assessment took place. No significant differences were reported between ACT and wait-list however post-test comparison favoured ACT, with a small to moderate effect

size ($d=0.43$). The main limitation of this study is its extremely small sample size. As there was only one ACT group administered by one therapist, the effect of therapist on outcome is likely to be a confounding factor.

Two studies delivered ACT in an individual psychotherapy format. Dahl et al. (2004) randomly allocated 19 public health sector workers with chronic pain to two conditions. In the ACT condition, participants underwent four 1-hour weekly sessions of individual psychotherapy alongside medical TAU while the control group only received medical TAU. At post-intervention and six-month follow-up there were no significant improvements in LSQ scores in either condition and no significant differences between groups. However, the generalisability of the results is questionable given the small sample size and that participants were drawn from a highly specific working environment. In addition to this, no attempts were made to assess therapist adherence or competence. This is particularly problematic as one of the two therapists was a nurse without formal psychotherapy training.

In another study of ACT in an individual psychotherapy format, Wicksell, Ahlqvist, Bring, Melin and Olsson (2008) found significant differences in rates of improvement on the SWLS between individuals receiving ACT and wait-list controls. A longer treatment protocol was used consisting of 10 one-hour sessions administered over eight weeks. Participants were 22 patients with chronic pain or whiplash associated disorders. In comparing the groups, the authors report a large effect size in favour of ACT ($d=1.12$). Although only two therapists were involved in administering the intervention, analysis indicated that there was no difference in outcome between therapists. Again, the small sample size makes it difficult to draw strong conclusions about the effectiveness of ACT with this population.

Three studies evaluated ACT self-help interventions for chronic pain. In a sample of 76 individuals with chronic pain, Buhrman et al. (2013) compared an internet-delivered ACT intervention against a moderated online forum. Participants in the ACT group completed one of seven modules each week and were required to complete assignments in order to move onto the next module. They also received two phone calls at set points in the treatment to support and encourage participation. The results showed no significant effects of ACT on quality of life from pre- to post-intervention. One major limitation of the study is that no follow-up data was gathered for the control group meaning that that no longer-term comparison can be made between the groups.

Johnston, Foster, Shennan, Starkey and Johnson (2010) randomised 24 participants with chronic pain to either a wait-list control group or an ACT group who received a self-help workbook. The workbook was completed over six weeks with 30 minutes of weekly telephone support. Post-intervention, the ACT group showed significantly improved QOLI scores compared with wait-list controls. The average effect size between the QOLI and SWLS was large ($d=0.91$). Follow-up data were not collected therefore the long-term effects of ACT cannot be established. The methodological quality of this study is questionable particularly in relation to the randomisation procedure. The first participant was randomised by the primary researcher, after which participants were allocated alternately to each group in the order that they were contacted. This enhances the possibility of allocation bias.

In a later study, Thorsell et al. (2011) used a Swedish translation of the self-help materials used by Johnston et al. (2010). They randomised 90 participants to receive ACT self-help or applied relaxation, also provided in a self-help format. Along with weekly telephone support, participants received a 90-minute face-to-face session, at the beginning and end of the intervention. The applied relaxation protocol matched the ACT group in terms of therapist time. In the ACT group, SWLS scores were found to significantly improve relative to scores in the applied relaxation group – with a large effect-size ($d=3.01$) which was maintained at 12-month follow-up ($d=2.3$).

The main strengths of this study are its large sample size and longer follow-up period. However, as with the previous trial by Johnston et al., there was a high rate of attrition (37% in the ACT condition) which the authors attribute to the amount of reading required. This meant that the statistical power and precision of effect estimation were weakened.

Fibromyalgia

Two studies examined ACT for fibromyalgia. Luciano et al. (2014) randomised 156 patients with fibromyalgia to one of three conditions: group delivered ACT, pharmacological treatment, or wait-list. Those in the ACT condition received eight 2.5-hour group sessions with group size varying from 10 to 15 participants.

Pharmacological treatment included an anti-convulsant, analgesics, benzodiazepines, hypnotics, and where indicated, an anti-depressant. ACT was found to be superior to pharmacological treatment at improving quality of life post-intervention and this was maintained at 6-month follow-up with a large effect size ($d=0.85$). However, it could be

argued that a better test for the superiority of ACT would have been a comparison to another efficacy-established psychotherapeutic treatment such as CBT, as this would be more equivalent to the ACT protocol in terms of therapy time and context of intervention.

Wicksell et al. (2013) randomised 40 individuals with fibromyalgia to an ACT condition or a wait-list condition. The ACT condition comprised 12 90-minute group sessions, with six participants in each group. A selection of recorded sessions was systematically evaluated for treatment adherence and competence. A significant effect in favour of ACT was reported in mental health-related quality of life with a large effect size ($d=0.84$) that was maintained at 6 months ($d=1.06$). No such difference was found in physical-health related quality of life.

The generalisability of findings from both of these studies is limited due to the lack of male participants, with males excluded by Wicksell et al. (2012) and only six included by Luciano et al. (2014).

Drug-refractory epilepsy

Two studies examined ACT for drug-refractory epilepsy with both adopting an ACT protocol combining individual and group therapy sessions. In the Lundgren, Dahl, Yardi and Melin (2008) study, the ACT protocol comprised two 1.5-hour individual sessions and two 3-hour group sessions administered over five weeks. Two 1.5-hour booster sessions after six and 12 months were also provided. Eighteen participants with epilepsy were randomised to receive either ACT or yoga. The yoga protocol was designed to match the ACT protocol in terms of session duration and the number of individual and group sessions. At 12-month follow-up, the quality of life of individuals in the ACT condition had improved significantly from baseline according to the WHOQOL-BREF ($d = 0.81$) but not according to the SWLS. The average effect size across both measures was small to medium ($d=0.36$), favouring ACT. This effect was maintained at 12-month follow-up.

Similarly, Lundgren, Dahl, Melin and Kies (2006) compared the above ACT protocol ($n=14$) with supportive therapy ($n=13$). Again, the comparison group treatment protocol was identical to the ACT protocol in session number, format (group and individual), and duration, providing a strong test for ACT. The supportive therapy treatment provided participants with a space to reflect on their experiences of having epilepsy. At post-

intervention and at 12-month follow-up, there were significant between group differences favouring ACT, on both the WHOQOL-BREF and SWLS, with large effect sizes (average $d=1.05$).

Tinnitus

Two studies examined ACT as a treatment for tinnitus although the format of treatment differed between the two trials. Hesser et al. (2012) randomised 99 patients with tinnitus to one of three groups. Two groups received an internet-delivered guided self-help intervention, one based on ACT and the other on CBT. The third group acted as a control with participants encouraged to use an online discussion forum. Both self-help interventions involved text and picture based material and each participant was allocated a therapist to provide online support via a message board. When ACT was compared to the CBT or control conditions there were no significant differences in quality of life according to the QOLI.

In an earlier trial, Westin et al. (2011) randomised 64 normal hearing participants with tinnitus into one of three conditions. One condition received 10 one-hour individual sessions of ACT. Sessions were weekly and lasted 60 minutes. A second condition received tinnitus retraining therapy where participants were allocated a wearable sound generator which they were asked to use for a minimum of eight hours daily for 18 months. They also received an initial 150-minute training session with a 30-minute follow-up. A wait-list control comprised the third condition with participants waiting to receive CBT in individual, self-help, or group format. The authors report no significant changes in QOLI scores in either active treatment at post-intervention or follow-up. No follow-up data were collected for the wait-list condition meaning that comparisons with the active treatment conditions at follow-up could not be conducted. Another limitation of this study is that adherence and therapist competence was not assessed for the tinnitus retraining intervention so the quality of this, as a comparison for ACT, cannot be established.

Ovarian cancer

One study examined ACT for ovarian cancer. Rost et al. (2009) randomised 47 women diagnosed with Stage III or IV ovarian cancer to a TAU control group or an ACT group. Both conditions received twelve individual face-to-face meetings with a therapist. The TAU intervention was based upon a protocol comprising common CBT techniques. The analyses indicated that while there was a statistically significant improvement from

baseline in quality of life for individuals in the ACT condition, no such improvement was found for the TAU condition. When compared, ACT was statistically superior to CBT (TAU) at improving quality of life, according to FACT-G scores, with a large effect size ($d=1.35$). Although this study provides initial support for individually delivered ACT for improving quality of life in ovarian cancer patients, there is some question over the generalisability of the results. Both treatment conditions were administered by the same therapist and no attempt was made to assess adherence to the protocols or the competence of delivery.

Discussion

In total, 15 studies (including one ancillary study) met inclusion criteria for the present review. The studies covered a range of long-term physical health conditions and adopted a variety of formats for delivering ACT. Of the 14 original studies, 8 found ACT to be superior to control on at least one quality of life measure. It is worth noting that for the majority of studies, ACT was superior in terms of improvements in primary outcome measures, however, a full summary and discussion of these results is beyond the scope of this review.

Given that just over half of the studies included in the review found that ACT benefitted quality of life while the remaining trials did not, it is difficult to draw strong overall conclusions about the effectiveness of ACT across physical health conditions. However, some tentative conclusions can be drawn. Both epilepsy studies found ACT to be superior to the comparison group. Given the efforts made to ensure that the comparison groups (yoga and supportive therapy) matched ACT in therapy time and delivery format, this provides strong preliminary evidence for a combined ACT protocol to improve quality of life for people with epilepsy. Future trials with larger samples are needed to further support this position.

Conversely, neither of the tinnitus studies found ACT to be superior to control at improving quality of life even when compared to largely inactive control groups. Although tinnitus can be extremely disabling (Moller, 2000), it might be that quality of life is less impaired than in other long-term conditions. This was certainly true in the Westin et al. (2011) study where mean QOLI scores at baseline were similar to those of a healthy population. This leaves little room for improvement, suggesting that quality of life may not be a suitable outcome measure in this instance. As the ACT protocols differed substantially (one was internet-based and the other individual therapy), it is

perhaps premature to conclude about the impact of ACT on quality of life in this population.

Although the APA support ACT as an evidence-based treatment for chronic pain, four of the seven original chronic pain studies did not find ACT superior at improving quality of life. It is unclear why this may have been the case although one possibility is that the selection of studies was not representative, as several chronic pain studies were excluded on the grounds that they did not include quality of life measures. In order to effectively evaluate whether ACT can improve quality of life in individuals with long-term conditions, future research must include such measures.

As discussed, the format for delivering the ACT intervention varied across studies. However, this did not appear to be related to whether ACT was effective at improving quality of life. Across all formats the number of studies that found ACT to be superior was equal to the number of studies which found no difference between ACT and control. To elaborate further, two of the four ACT self-help studies, two of the four individual ACT studies, and two of the four group ACT studies found ACT to be superior to their respective comparison groups. The studies which used a combined protocol both found ACT to be superior. Given these findings, there is some support for all delivery formats although more research is needed to confirm their effectiveness. NHS mental health services in England adopt a stepped care model where the least intrusive treatment is offered first. Therefore, there is a need to develop interventions at all levels of intensity from self-help to individual psychotherapy. ACT outcome research is beginning to address this need.

Methodological quality varied greatly between trials although there were some common methodological threats which should be addressed in future research. While some studies were careful to design active comparison treatments matching the ACT protocol in terms of therapy time, several studies adopted a wait-list control group. It is perhaps unsurprising that ACT was superior in three of the four trials that only used a wait-list control group. Effect sizes are often larger when active treatments are compared with inactive control groups. It is difficult therefore to determine the true effectiveness of ACT under these conditions.

Another common problem was that many studies failed to carry out checks to ensure therapist adherence and competence. Furthermore, there were often few therapists

administering interventions without any form of analysis to examine the effect of therapist on outcome. These methods introduce significant sources of bias.

Another major limitation in several included trials was the method of analysis of the outcomes. Bland and Altman (2011) have found that rather than comparing randomised groups directly, some researchers conduct a significance test comparing a baseline with a final measurement separately in each group. Through simulations, they demonstrate how the results from such findings can be biased, invalid and misleading. This was method was used in several of the included trials. Furthermore, in 2 out of 15 trials, longer-term outcome data was not collected for the control groups. Future trials need to ensure that comparisons are made between the groups on pre-specified outcomes.

The point at which the outcomes were assessed was another issue with some of the included trials. Only 10 out of 15 trials had any longer-term (>6-months) outcomes assessed. As such, we cannot determine whether any treatment effects found immediately post-intervention are maintained over time.

Before concluding, we acknowledge some methodological limitations of our review. In another review in which quality was assessed by three reviewers, the authors were unable to gain acceptable kappa ratings on nearly half of the items in Öst's tool (Smout, Hayes, Atkins, Klausen & Duguid, 2012). This suggests that the Öst evaluation tool may be unreliable. A further limitation is that the heterogeneity of studies (e.g., variability in clinical population, comparison condition and intervention characteristics) precluded meaningful use of formal meta-analysis; we computed effect size estimates for individual studies to allow for descriptive comparisons.

Conclusion

ACT aims to be a transdiagnostic model with wide application across the full spectrum of mental and physical health conditions. Despite this, 8 of the 15 studies included in this review examined the effectiveness of ACT for people with chronic pain. This continues to be the area of physical healthcare for which the most ACT outcome research exists. Therefore, there continues to be a dearth of research evaluating ACT for other chronic physical health conditions. Although tentative support is offered for ACT at improving quality of life in conditions such as epilepsy and ovarian cancer, the methodological quality of some studies is poor, and the findings need to be treated with

caution. Therefore, large-scale and methodologically robust trials are needed to continue to explore the application of ACT for other long-term conditions.

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Journal Paper

Acceptance and Commitment Therapy self-help intervention for depression in haemodialysis patients: A feasibility randomised controlled trial

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Abstract

Objective: People with end-stage renal disease (ESRD) experience high rates of depression and this is associated with poorer health-related outcomes. Acceptance and Commitment Therapy (ACT) has shown promising results in a number of long-term conditions and has been translated into a variety of self-help formats. We aimed to determine the feasibility of a trial examining telephone-supported self-help based on ACT for individuals with ESRD who experience depression.

Design: A feasibility randomised controlled trial comparing telephone-supported ACT self-help with treatment as usual.

Methods: Participants were recruited from four outpatient haemodialysis units across Nottinghamshire, UK. The Patient Health Questionnaire (PHQ-9), EuroQol (EQ-5D-5L) health-related quality of life measure, Acceptance and Action Questionnaire II (AAQ-II) and Valued Living Questionnaire (VLQ) were completed at baseline and 2- and 4-months post-randomisation. Participants in the intervention arm were asked to complete an ACT self-help manual over six weeks with weekly telephone support. Following completion of the trial, six participants were interviewed to examine the acceptability of the trial procedure and intervention. Interview data was analysed using framework analysis.

Results: In total, 99 (36.87%) of 276 screening questionnaires were returned. Of these, 30 (30.3%) met the cut-off for depression on the PHQ-9 with nine enrolling in the trial. AAQ-II scores of screened participants were positively associated with scores on the PHQ-9 and GAD-7, indicating a positive relationship between psychological inflexibility and distress. Interview data indicated that the recruitment and randomisation procedure, and assessment methods were acceptable. Only one in four of the participants in the ACT arm of the trial completed all chapters of the book with health problems the main barrier to completion.

Conclusion: Our findings indicate that a definitive trial examining the effectiveness of a telephone-supported ACT self-help intervention would not be feasible. Many aspects of the trial were acceptable to participants, including the main recruitment strategy, randomisation procedure and data collection methods. However, low recruitment numbers and poor adherence to the self-help manual indicate that a full-scale trial would not be viable.

Key words: Acceptance and Commitment Therapy, end-stage renal disease, depression, self-help, randomised controlled trial.

Impact and Implications Statement

What is already known on this subject?

- Depression is highly prevalent in ESRD and is related to a number of negative health-related outcomes.
- ACT has been used successfully as a treatment for depression.
- There are no trials of ACT in ESRD.

What does this study add?

- A full trial of telephone-supported self-help based on Acceptance and Commitment Therapy (ACT) is not feasible.
- Self-help interventions may not be appealing to ESRD patients identified as experiencing depression.
- Health problems may make it difficult for ESRD patients to commit to and engage with supported self-help interventions.
- ACT processes may be related to psychological distress in ESRD.

Introduction

End-Stage Renal Disease

Chronic Kidney Disease (CKD) is a long-term condition in which the function of the kidneys – to filter out waste products from the blood – slowly declines (Lewis, 2013). When renal function becomes sufficiently low it is described as End Stage Renal Disease (ESRD) and renal replacement therapy is likely to be needed to prolong life. This includes haemodialysis, peritoneal dialysis and kidney transplantation¹.

ESRD is an irreversible life-threatening condition with 58,968 adult patients undergoing renal replacement therapy in the UK in 2014, an increase of 4 per cent since 2013 (MacNeill, Casula, Shaw & Castledine, 2016). The annual rate of growth in the numbers of patients undergoing renal replacement therapy has remained moderately consistent over the last 10-15 years, indicating a growing demand for services.

Depression

The prevalence of depression in ESRD is high with estimates ranging from 10 to 45% (Kimmel, 2001). Depression is related to poorer outcomes in ESRD including increased morbidity (Cukor et al., 2012) and mortality (Chilcot, Davenport, Wellsted, Firth & Farrington, 2011), and reduced quality of life (Drayer et al., 2006). This is in addition to poorer adherence to haemodialysis and increased health-care utilisation (Hedayati et al., 2005)².

Correlations have been found between behavioural disengagement, a form of avoidant coping, and depression in ESRD (Ibrahim, Chiew-thong, Desa, Razali, 2013; Keskin & Engin, 2011). Similarly, the suppression of distressing emotions by ESRD patients, another form of avoidance, is related to higher levels of depression (Gillanders, Wild, Deighan & Gillanders, 2008). Although, more research is needed to fully understand the aetiology of depression in ESRD, these findings suggest that avoidant coping may be a factor.

An alternative to avoidance is acceptance, the active embrace of private experiences (e.g. thoughts, feelings and sensations) without making attempts to change their form or frequency (Hayes, Strosahl & Wilson, 1999). As an important aspect of

¹ See Extended Introduction 1.1 for further information on renal replacement therapy

² See Extended Introduction 1.3 for further information on depression in ESRD

accommodative coping, acceptance has been found to be a key factor in adjustment to kidney disease (Wright & Kirby, 1999) and has also been shown to have a direct effect on mental health (Poppe, Crombez, Hanoulle, Vogelaers & Petrovic, 2013). In light of these findings, Chan (2013) argues that kidney patients should be offered interventions that specifically aim to increase acceptance³.

The high prevalence of depression in ESRD and its relationship with various aspects of the course of the disease highlight the need to develop effective treatments for depression with this population and to make such treatments more available as part of the standard care provided for these patients (Zalai, Szeifert & Novak 2012). The National Institute for Health and Care Excellence (NICE) recommend the use of pharmacological interventions, as well as individual and group psychotherapy, for the treatment of depression in adults with chronic physical health problems (NICE, 2009a). However, evidence supporting the use of pharmacological interventions for depression in ESRD remains sparse. A recent systematic review concluded that there is insufficient evidence on the efficacy of anti-depressants for depression in ESRD (Nagler, Webster, Vanholder & Zoccali, 2012). Furthermore, some studies suggest that, for individuals with ESRD, dosage adjustments may be needed (Baghdady, Banik, Swartz & McIntyre, 2009) and that the side effects associated with anti-depressants may not be tolerated by ESRD patients (see Kimmel, Weihs & Peterson, 1993 for a review)⁴.

Given the lack of evidence for pharmacological interventions for depression in ESRD, coupled with the potential complications associated with these interventions, some have highlighted the pressing need to evaluate non-pharmacological treatments in this population (Christensen & Ehlers, 2002), however a 2005 Cochrane review reported insufficient data to conclude about the effectiveness of psychosocial interventions for depression in haemodialysis (Rabindranath et al., 2005)⁵.

Acceptance and Commitment Therapy

Acceptance and Commitment Therapy (ACT: Hayes et al., 1999) is an acceptance and mindfulness based psychotherapeutic modality which is part of the *third wave* in cognitive and behavioural therapies (Hayes, 2004). ACT posits a trans-diagnostic

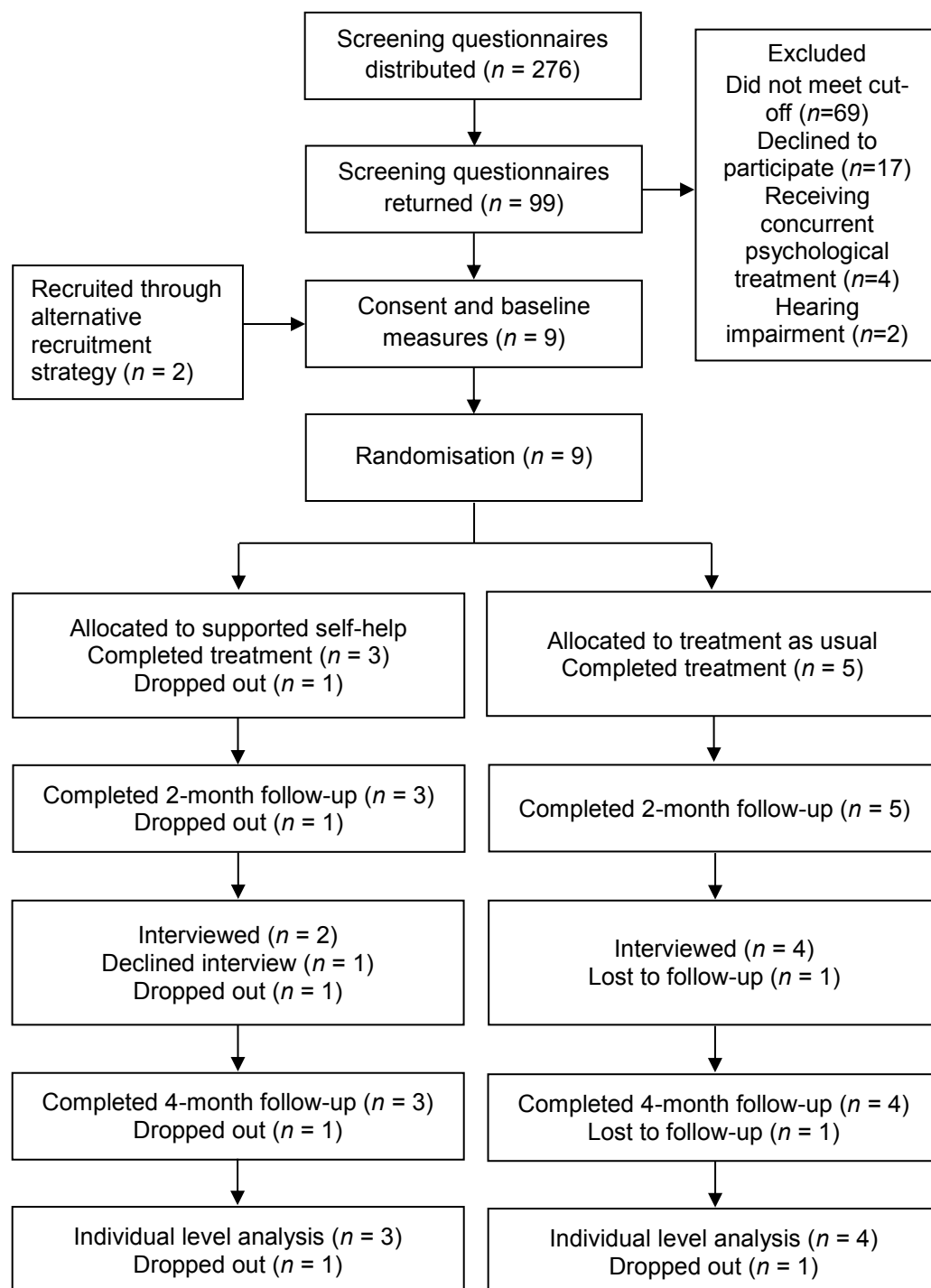
³ See Extended Introduction 1.4.9 for further information on acceptance in CKD

⁴ See Extended Introduction 1.2.1 for further information on psychopharmacological treatments

⁵ See Extended Introduction 1.2.2 for further information on psychotherapeutic treatment

Figure 2

Flow of participants through the trial



approach to psychopathology centred on the process of psychological inflexibility: the inability to respond flexibly to environmental contingencies due to the excessive and unhelpful regulation of behaviour by verbal processes (Hayes, Luoma, Bond, Masuda

& Lillis, 2006). Psychological inflexibility is characterised by experiential avoidance, attempts to change unwanted private experiences even when doing so leads to additional suffering (Hayes, Pistorello & Levin, 2012). ACT teaches acceptance and mindfulness skills as a counter to experiential avoidance, encouraging clients to engage in value-guided action while accepting and embracing, rather than avoiding, unwanted private events (Hayes et al., 1999). Acceptance is not an end in itself but a way of fostering valued action⁶.

No trials have examined the effectiveness of ACT in ESRD however ACT has shown promise in a variety of other long-term conditions (Montgomery, Kim & Franklin, 2011) and has been shown to be superior to placebo or treatment as usual for depression (A-Tjak et al., 2015). These findings offer a credible rationale for preliminary research examining the effectiveness of ACT for ESRD patients.

Self-help

Given the prevalence of depression in ESRD and the high cost of one-to-one therapy, there is a strong argument for developing alternative models for delivering psychological interventions to this client group. Furthermore, NICE guidelines for the treatment of depression recommend a stepped care model in which the least intrusive, most effective treatment is offered first (NICE, 2009b). As such there is a need to develop low-intensity interventions for this population.

Self-help interventions provide the opportunity to offer standardised psychotherapeutic interventions to large numbers of people with minimal input from the therapist (Watkins & Clum, 2007). Such interventions are available for a wide variety of mental health conditions (Kazdin & Blase, 2011) and an increasing number are evidence based treatments with effect sizes comparable with one-to-one therapy (Cuijpers, Donker, van Straten & Andersson, 2010). A number of ACT self-help manuals have been developed with preliminary data suggesting that they can produce psychological benefits in conditions such as chronic pain (Johnston, Foster, Shennan, Starkey & Johnson, 2010) and depression (Fledderus, Bohlmeijer, Pieterse & Schreurs, 2012)⁷.

No trials have examined the suitability of a telephone-supported self-help intervention for haemodialysis patients experiencing depression. The primary aim of the present

⁶ See Extended Introduction 1.4 for further information on ACT

⁷ See Extended Introduction 1.5 for further information on self-help interventions

study was to determine the feasibility of such a trial, in terms of recruitment, assessment, adherence, attrition and the acceptability of the intervention materials and format. A secondary aim was to generate some provisional data about the potential efficacy of the intervention by conducting individual level analysis comparing pre- and post-intervention outcomes. A final aim was to examine the relationship between psychological flexibility and distress in haemodialysis patients to test the rationale for using ACT with this client group.

Method

Design

A mixed-methods, between-within design was used. All participants continued to receive medical treatment as usual from the renal service and were randomly assigned to the control condition (treatment as usual) or the intervention condition (ACT self-help manual with weekly telephone support + treatment as usual).

Participants

Participants were recruited from four outpatient haemodialysis units across Nottinghamshire, UK⁸. Of these, two are located at a large metropolitan hospital with the other two serving as satellite units in smaller urban areas. All potential participants had a diagnosis of ESRD and were receiving haemodialysis treatment at one of the recruitment sites.

For inclusion in the trial, participants needed to be aged 18 years or above, receiving haemodialysis for at least 6-months, have adequate English reading ability, and meet the cut-off for depression on the Patient Health Questionnaire (PHQ-9; Kroenke, Spitzer & Williams, 2001). A cut-off of ≥ 10 was applied as this has been identified as a validated cut-off for depression in dialysis patients (Watnick, Wang, Demadura, & Ganzini, 2005). Reading ability was deemed adequate if participants were able to complete the screening measures independently. This was checked prior to gaining consent.

Individuals were excluded from the trial if they were receiving concurrent psychological treatment at the time of recruitment or in the previous 6-months. Participants were advised to inform the research team if they started psychological treatment during the

⁸ See Extended Methods 2.1 for further information on recruitment

trial. Those with visual or hearing impairments that were not otherwise corrected for (e.g. with eyeglasses or hearing aid), and that would make engagement with the intervention difficult, were also excluded.

Procedure

To examine the feasibility of recruitment methods, two recruitment strategies were utilised. In the first strategy, a designated member of staff was identified to approach participants at one of the satellite units. The chief investigator (WV) was on hand to speak to patients who expressed an interest or wanted more information. In the second strategy, dialysis unit staff distributed screening measures to haemodialysis patients at all four units when they attended for routine dialysis treatment. Staff were advised to distribute to all patients unless there were significant cognitive or language barriers. Returned measures were scored by WV. Those eligible were approached by WV at the unit and provided with a participant information sheet and a brief verbal account of the research. Patients were given at least 24 hours to review the information. Those interested were then interviewed to check eligibility criteria and complete consent forms.

Once consented, participants completed baseline measures and were randomised (1:1 allocation ratio) using a computer-generated random number sequence⁹. Participants were notified of their allocation in person or by telephone. Individuals allocated to the intervention condition were given a copy of the self-help manual along with guidance on which chapters to read each week. A time was also arranged for the first support call to take place. Subsequent calls were arranged on a week-by-week basis with all calls audio-recorded.

Participants were asked to repeat the measures two- and four-months post-randomisation. Measures were provided by staff on the unit or by post depending on preference. Six participants were interviewed by telephone, at the end of the trial, to examine aspects of feasibility. Interviews were conducted by a trainee clinical psychologist (BP) who was familiar with the design and intervention materials used, but not otherwise involved in the trial.

⁹ See Extended Methods 2.4 for further information on the randomisation process

Table 4

Screening and outcome measures

Measure	Screening	Baseline	2-month follow-up	4-month follow-up
PHQ-9	✓	✓	✓	✓
GAD-7	✓			
ET and problem list	✓			
AAQ-II	✓	✓	✓	✓
EQ-5L-5D		✓	✓	✓
VLQ		✓	✓	✓

PHQ-9: Patient Health Questionnaire; GAD-7: Generalised Anxiety Disorder; ET: Emotion Thermometer; AAQ-II: Acceptance and Action Questionnaire; EQ-5D-5L: EuroQol health-related quality of life measure; VLQ: Valued Living Questionnaire

Intervention

Participants in the intervention condition received a copy of the self-help manual *Get out of your mind and into your life: the new Acceptance and Commitment Therapy* (Hayes & Smith, 2005). Permission to use the book was provided by the author.

Individuals were provided with guidance on which chapters to complete each week over a period of six-weeks. A weekly telephone call from WV, lasting up to 30 minutes, offered support to participants to understand the materials and encourage adherence¹⁰.

Measures

Table 4 shows which measures were used as part of the screening procedure and which were used as outcome measures¹¹. A description of each measure is provided below.

Depression and anxiety

The PHQ-9 is a nine item scale with each item representing one of the nine depression diagnostic criteria of the Diagnostic and Statistical Manual-IV (DSM-IV; American Psychiatric Association, 1994). We used it as a screening and outcome measure. Using a cut-off of ≥ 10 , the PHQ-9 has 88% sensitivity and specificity with good internal consistency (Cronbach's $\alpha = .86-.89$; Spitzer et al., 2001). Respondents rate on a four point Likert scale (0 is *not at all* to 3 is *nearly every day*) how often they were bothered by the problems listed in the previous two weeks. A severity score is calculated by

¹⁰ See Extended Methods 2.5 for further information on the self-help manual

¹¹ See Extended Methods 2.3 for further information on the measures used

summing the scores for all items with higher scores representing more severe depression. Reductions in depressive symptoms are not the target of ACT, which aims to allow patients to accept distressing private events. However, it is possible that symptoms may reduce as a secondary effect of increased valued action.

The Generalised Anxiety Disorder 7-item (GAD-7; Spitzer, Kroenke, Williams & Löwe, 2006) scale assesses symptoms of generalised anxiety. We used the GAD-7 to examine the relationship between psychological flexibility and distress, and to examine rates of distress across the units. Both the PHQ-9 and GAD-7 have been used in renal populations (e.g. Watnick et al., 2005; Trigka, Douzdampanis, Aggelakou-Vaitsi, Vaitsis & Fourtounas, 2013). The GAD-7 has excellent internal consistency (Cronbach's $\alpha = .92$) and good test-retest reliability (intraclass correlation = .83; Spitzer et al., 2006).

The Emotion Thermometer (ET; Mitchell, Baker-Glenn, Granger & Symonds, 2010) comprises eight visual analogue scales in the form of four emotion domains (distress, anxiety, depression and anger) and four impact domains (pain, burden, need help and overall health). Each domain is indicated using a 10 point Likert scale in a colour coded visual thermometer format. A problem list is also provided with respondents asked to tick which of the problems they have been effected by over the previous two weeks. We administered the ET to examine which distress measure is most acceptable for this population. The ET has excellent internal consistency (Cronbach's $\alpha = .91$; Mitchell & Symonds, 2010).

Acceptance

The Acceptance and Action Questionnaire II (AAQ-II; Bond et al., 2011) is a seven item measure of psychological inflexibility (or experiential avoidance). It was used to provide provisional analysis of the underlying processes of the ACT model and to determine whether the intervention cultivates acceptance. The AAQ-II has good internal reliability (Cronbach's $\alpha = .84$).

Health-related quality of life

The EQ-5D-5L (EuroQol Group, 1990) is a five-dimension measure of health-related quality of life with good psychometric properties (Janssen et al., 2012). It was included to assess the feasibility of collecting cost-effectiveness outcome measures in a definitive trial. Test-retest reliability for the EQ-5D-5L is acceptable (intraclass correlation = .69; Janssen, Birnie, Haagsma & Bonsel, 2008).

Valued living

The Valued Living Questionnaire (VLQ: Wilson, Sandoz, Kitchens & Roberts, 2010) is a 20-item scale consisting of two parts. In Part 1, participants rate the importance of ten life domains using a 10-point Likert scale (1 is *not at all important* and 10 is *extremely important*). In Part 2, participants rate, using the same scale, how consistently they have lived within the valued behavioural pattern of each domain over the previous week. A composite score taking into consideration the importance placed on each domain and the extent to which an individual is living consistently within that domain is calculated. The VLQ has good internal consistency (Cronbach's $\alpha = .7$) and test-retest reliability (intraclass correlation $= .75$).

Socio-demographic characteristics

Socio-demographic characteristics were gathered from patient medical records. Residence postcodes were converted into an index of multiple deprivation rank (IMDR), based on a UK government qualitative study examining patterns of social and economic deprivation across England (Department of Communities and Local Government, 2015). It delineates seven domains of deprivation: income, employment, education, skills and training, health deprivation and disability, crime, barriers to housing and services, and living environment. The study divides England into 32,844 neighbourhood areas and ranks them in order of deprivation with a score of 1 being the most deprived. Clinical information was collected from participants' medical records.

Data analysis

Descriptive statistics were used to provide an overview of screened and enrolled patients. To examine the feasibility of recruitment, between group analyses explored differences between those who completed the screening questionnaire and those who did not. Differences in age and IMDR were examined using Mann-Whitney U analyses as parametric assumptions were violated. A mixture of parametric and non-parametric tests were used to examine differences between participants allocated to the ACT and control conditions of the trial (see Table 6).

To examine the overall feasibility of the trial, interview data were transcribed verbatim and analysed using framework analysis (Ritchie & Spencer, 1994). Pre-defined codes relating to different aspects of the research question were applied to each transcript and these were combined to generate a framework (Gale, Heath, Cameron, Rashid &

Table 5

Baseline characteristics of screened patients

Characteristic	Completers	Non-completers
Participants, <i>n</i>	99	177
Age, mean (<i>SD</i>)	69.7 (16.1)	66.5 (14.2)
Female %	49.5	45.8
Index of Multiple Deprivation, median	10,431	9,283
PHQ-9, mean (<i>SD</i>)	7.5 (6.9)	--
GAD-7, mean (<i>SD</i>)	5.1 (6.0)	--
AAQ-II, mean (<i>SD</i>)	16.0 (11.0)	--
ET distress, mean (<i>SD</i>)	2.7 (3.1)	--
ET anxiety, mean (<i>SD</i>)	2.5 (3.1)	--
ET depression, mean (<i>SD</i>)	2.7 (3.2)	--
ET anger, mean (<i>SD</i>)	2.5 (3.3)	--
ET pain, mean (<i>SD</i>)	4.0 (3.4)	--
ET burden, mean (<i>SD</i>)	4.0 (3.6)	--
ET need help, mean (<i>SD</i>)	3.0 (3.3)	--
ET overall health, mean (<i>SD</i>)	4.8 (3.0)	--

PHQ-9: Patient Health Questionnaire; GAD-7: Generalised Anxiety Disorder; AAQ-II: Acceptance and Action Questionnaire; ET: Emotion Thermometer

Redwood, 2013). Pre-defined codes were recruitment, randomisation, measures, support calls, self-help manual and treatment as usual. A deductive, manifest level approach was taken when interpreting the data. To examine the credibility of the intervention, Pearson's product-moment correlations were used to determine the relationship between psychological flexibility (AAQ-II) and distress (PHQ-9 and GAD-7). The Leeds Reliable Change Indicator software (Agostinis, Morley & Dowzer, 2008) was used to examine individual level change over time¹².

Results

To provide a cohesive account of the findings, where applicable, quantitative and qualitative data have been collated under the sub-headings below.

Sample

In total, 99 (36.9%) of 276 screening questionnaires were returned¹³. Table 5 shows the demographic characteristics of screening questionnaire completers and non-completers. Of those who completed the questionnaire, 30 (30.3%) met the cut-off for depression, 17 of whom declined to participate. Six people were excluded: four were

¹² See Extended Methods 2.7 for further information on the individual level analysis

¹³ See Extended Results 3.1 for further information on the screening

Table 6

Baseline characteristics of enrolled participants

	ACT	Control	<i>p</i> value
Participants, <i>n</i>	4	5	--
Attrition, <i>n</i>	1	0	--
Age, mean (<i>SD</i>)	65.3 (16.0)	49.2 (19.8)	0.23a
Female %	75	60	0.6b
Years dialysing, mean (<i>SD</i>)	9.5 (13.7)	7.6 (5.7)	0.56c
PHQ-9, mean (<i>SD</i>)	13.8 (2.2)	16.6 (2.5)	0.12a
EQ-5D index value, mean (<i>SD</i>)	0.4 (19.1)	0.4 (0.3)	0.42a
EQ-VAS	41.25 (19.3)	44 (8.9)	0.9c
AAQ-II, mean (<i>SD</i>)	25.5 (11.6)	28.2 (13.9)	0.7a
VLQ, mean (<i>SD</i>)	47.3 (11.2)	51.2 (13.9)	0.66a

PHQ-9: Patient Health Questionnaire; EQ-5D index value: EuroQol health-related quality of life measure; EQ-VAS: EuroQol visual analogue scale; AAQ-II: Acceptance and Action Questionnaire
a = Independent t-test; b = Fisher's exact test; c = Mann-Whitney U

receiving concurrent psychological treatment and two had significant hearing impairment that would prevent engagement in the telephone support aspect of the intervention. This left seven participants who consented to the trial. Two further participants enrolled through the first recruitment strategy described above, giving a total number of nine participants.

Analysis showed a statistically significant difference in age between screening completers (*Mdn* = 74) and non-completers (*Mdn* = 69), $U = 7417.5$, $z = -2.11$, $p = .04$. No differences were found IMDR between screening questionnaire completers (*Mdn* = 10,431) and non-completers (*Mdn* = 9283), $U = 8,391$, $z = -.58$, $p = .56^{14}$.

Feasibility

In all, six participants were interviewed about their experiences of the trial, four from the control arm and two from the ACT arm. While all participants were asked the same questions, not all of them made comments relating to the pre-defined codes.

Recruitment

Of 276 screening questionnaires distributed, 99 (36.9%) were returned. All participants interviewed thought that the recruitment procedure was appropriate, with five stating that it was not too intrusive to be approached on the dialysis unit and the sixth making

¹⁴ See Extended Results 3.3 for further information on assumption testing

no comment about this. All participants interviewed indicated that the information provided was clear. To ensure that the psychological needs of patients were addressed, those who met the cut-off for depression but declined to participate in the trial were subsequently asked whether they would like any other form of psychological support. Patients were told that the questionnaire indicated that they may be struggling with low mood and they were asked if they would like to speak to someone about this. All 17 patients who declined to participate also declined other psychological support.

Randomisation

Four participants indicated that they thought the randomisation procedure was a fair way to allocate participants although one of these participants also thought that it might deprive individuals of the care that they need. One participant stated that they did not think the allocation procedure was fair as they also felt that some people might not get the necessary help. Another participant made no comment about the randomisation procedure.

Acceptability of measures

Table 7 shows the percentage of items not completed for each screening measure. The highest percentage of missing data points were on the ET, while all participants completed all items on the PHQ-9 and GAD-7. The ET was placed at the end of the questionnaire and participants may have lost motivation before completing the full battery. Alternatively, participants may have found the ET confusing or difficult to complete. Five of the participants interviewed were happy with the time taken to complete the measures with the other participant not commenting on this aspect of the procedure. Four participants stated that the questionnaire items were appropriate while one thought that it was unclear why some of the questions were being asked, in particular items on the VLQ. Another participant was confused by the scales used on some of the measures and specifically made reference to the pain scale on the ET. Interestingly, there was no missing data for participants enrolled in the actual trial.

Attrition

Only one participant (11%), an individual allocated to the ACT condition, dropped out of the trial. This participant withdrew due to ill health before starting the self-help manual. The remaining participants remained in the trial although one passed away before follow-up measures were completed.

Table 7

Percentage of missing data points per measure at screening

Measure	Missing data points
PHQ-9, %	0
GAD-7, %	0
AAQ-II, %	0.4
ET, %	9.3
Problem list, %	3.5

PHQ-9: Patient Health Questionnaire; GAD-7: Generalised Anxiety Disorder; AAQ-II: Acceptance and Action Questionnaire; ET: Emotion Thermometer

Support calls

One participant interviewed from the ACT arm described the calls as being appropriately scheduled in terms of timing, frequency and duration. The other participant felt that the calls were helpful to provide clarity and understanding on the content of the book. Both participants thought that the support call aspect of the intervention could be off-putting for dialysis patients because of the time taken, the difficulties hearing calls while on the dialysis unit or because some patients might not feel comfortable talking on the phone. All but three support calls (8%) took place at the agreed time.

Acceptability of self-help manual

Only one of the four participants in the ACT condition completed all sections of the self-help manual. Health problems were a barrier to completion for all other participants who received the manual. One participant read five pages of the introductory chapter before having a series of health problems. They did not want to withdraw but found it difficult to continue with the manual. Another participant completed four chapters during the first week but was unable to continue thereafter, when the participant was admitted to hospital for a routine surgical procedure, not planned at the time of recruitment, and two separate family bereavements. As described above, a fourth participant withdrew due to health complaints, prior to starting the manual.

Only two participants in the intervention arm were interviewed and thus there is only a small amount of data pertaining to the helpfulness and acceptability of the self-help manual. In terms of the content of the book, one participant thought that the language and examples used were more relevant to an American population. They also felt that

Table 8

Individual level analysis comparing pre- and post-intervention outcomes

Participant ID	Time	PHQ-9	AAQ-II	EQ-5D-5L
Treatment as usual				
2	Pre	18	35	-0.1
	Post	15	40	0.22 ^{MID↑}
	Follow-up	15	38	0.22 ^M
4	Pre	18	24	0.4
	Post	22	42 ^{R↓C↓}	-0.13 ^{MID↓}
	Follow-up	21	39 ^M	-0.13 ^M
6	Pre	13	7	0.68
	Post	16	7	0.57 ^{MID↓}
	Follow-up	LTF	LTF	LTF
7	Pre	19	44	0.66
	Post	17	40	0.66
	Follow-up	17	41	0.68
8	Pre	15	31	0.53
	Post	6 ^{C↑}	18 ^{R↑}	0.53
	Follow-up	7 ^M	24	0.54
Supported self-help				
3	Pre	13	38	0.29
	Post	6 ^{C↑}	24 ^{R↑C↑}	0.68 ^{R↑MID↑}
	Follow-up	7 ^M	28 ^M	0.59
5	Pre	13	27	0.57
	Post	19	35 ^{C↓}	0.23 ^{R↓MID↓}
	Follow-up	17	28	0.3 ^M
9	Pre	12	11	0.38
	Post	10	10	0.23 ^{MID↓}
	Follow-up	13	15	0.17 ^M

^R denotes Reliable Change at $p < .05$; ^C denotes Clinically Significant Change (from clinical to non-clinical range); ^{MID} denotes a minimally important (clinical) difference; ↑ indicates an improvement and ↓ indicates a deterioration; ^M denotes changes maintained at 4-month follow-up; LTF denotes lost to follow-up

some of the language used was too difficult and this made them feel inadequate. The participant who completed all chapters of the book, reported that he had found the book helpful and was only dissatisfied with one part, a values clarification exercise in which readers are asked to think about their funeral. He found it uncomfortable thinking about his death. He also felt that it would have been better if he had had longer to read the book as he found it hard to read it all in the allotted 6-weeks.

Process-outcome relationship

Pearson correlation showed a strong positive relationship between psychological inflexibility and depression, $r(95) = .83, p < .001$. A second Pearson's correlation

showed a similarly strong positive relationship between psychological inflexibility and general anxiety, $r(96) = .86, p < .001$.

Individual level analysis

Table 8 provides a summary of individual level analyses comparing pre- and post-intervention outcomes and denotes incidences of clinically significant and reliable change. Incidents of minimally important differences are also provided for the EQ-5D-5L as no clinical cut-offs are available. Two participants, one from each condition, exhibited clinically significant changes in PHQ-9 scores, which were maintained at follow-up. One participant from the ACT condition showed reliable improvement, while two in the control condition showed reliable deterioration, on the AAQ-II. Two individuals from each condition experienced minimally important deteriorations in EQ-5D-5L scores and one in the control group experienced a minimally important improvement. This is perhaps indicative of the high symptom burden and dynamic health state experienced by haemodialysis patients. It is also consistent with the finding that health problems may occur frequently for this client group and may be a significant barrier to engagement in self-help materials.

Discussion

Main findings

Our findings indicate that a definitive trial examining the effectiveness of a telephone-supported ACT self-help intervention would not be feasible. Many aspects of the trial were acceptable to participants, including the main recruitment strategy, randomisation procedure and data collection methods. However, low recruitment numbers and poor adherence to the self-help manual indicate that a full-scale trial would not be viable.

Recruitment¹⁵

Our screening indicated a 30.3% prevalence of depression amongst those who returned the questionnaire, a rate that falls within the range of prevalence estimates previously identified in the literature (Chilcot, Wellsted & Farrington, 2010) and consistent with other studies that have used a PHQ-9 cut-off of 10 (e.g. Weisbord et al., 2013). Seventeen of those who met the cut-off did not want to participate in the trial and declined the offer of individual psychological support outside of the trial. A further four people were already receiving psychological treatment.

¹⁵ See Extended Discussion 4.1 for further information on recruitment

A combination of factors may have contributed to our low recruitment numbers primarily relating to cohort characteristics. The mean age of screened patients was 69.7, consistent with the national average for haemodialysis patients (MacNeill et al., 2016). The challenges of recruiting older adults into clinical trials are well documented (Piantadosi et al., 2015) and may be especially difficult in trials examining late-life depression (Thompson, Heller & Rody, 1994).

Older adults are less likely to recognise symptoms of depression and are more likely to attribute them to physical illness or aging (Rodda, Walker & Carter, 2011). This is perhaps doubly relevant here given the cross-over between symptoms of ESRD and the somatic symptoms of depression. This misattribution of symptoms has been highlighted as a barrier to treatment-seeking (Sarkisian, Lee-Henderson & Mangione, 2003). Older adults may also deny symptoms of depression due to the perceived stigma both of depression itself and of needing help for a mental health problem (Evans & Mottram, 2000).

As well as a misattribution of symptoms, the symptomatology of depression and ESRD may themselves act as a barrier to recruitment. Self-help requires motivation, concentration and a time commitment. Fatigue is common in ESRD and was reported by more than half of the participants who completed our screening measure. Similarly, low motivation and concentration are characteristic of depression.

A further consideration may relate to the treatment burden already experienced by haemodialysis patients. As well as the dialysis regimen itself, patients have to manage a high pill burden and strict fluid and dietary restrictions. Bearing in mind the co-morbidities and age of the cohort, it is likely that they will have multiple healthcare appointments in addition to those related to kidney care. Given these commitments, haemodialysis patients may lack the time and motivation to engage in an additional self-driven treatment for a problem that they may not perceive to be psychological in nature.

Adherence

Our conclusions about adherence are based on an extremely small number of participants and must therefore be considered with caution. Only one of the four participants who received the ACT intervention completed all sections of the manual,

with two completing less than one quarter and another dropping-out prior to starting. For all non-completers of the manual, health problems were reported as the main barrier. This is perhaps unsurprising given the high symptom burden of people with ESRD. Furthermore, depression in ESRD is associated with a range of negative health-related outcomes and it may be that those most in need of an intervention of this kind are also most likely to disengage due to health problems. Past research suggests that older adults with poorer physical health are more likely to drop-out of longitudinal depression trials (Sharma, Tobin & Brant, 1989).

Individuals with ESRD are more likely than the general population to experience a dynamic health state which may impact their ability to engage in psychotherapeutic treatment. It is important that clinicians offering psychotherapeutic interventions, including guided self-help, deliver them flexibly and in response to patient need. In the present trial, the standardised nature of the intervention did not allow sufficient flexibility to those patients whose health problems prevented full and immediate engagement with the materials.

Implications for service delivery

The Improving Access to Psychological Therapies (IAPT) programme has demonstrated that low-intensity interventions, including guided self-help, can be effective for treating mild to moderate anxiety and depression in a primary care setting (Department of Health, 2012) and there are now plans to extend the IAPT programme to the treatment of people with long-term physical conditions (Department of Health, 2011). The present research brings some important considerations to light.

Matcham et al. (2014) carried out a review of self-help interventions for people with long-term physical conditions. After removing studies with a high risk of bias from the analysis, no significant differences in drop-out rates between self-help and control groups were found. The authors took this as evidence that self-help interventions are acceptable to patients with long-term conditions. Our findings indicate that there may be some resistance to self-help interventions in ESRD and that there needs to be further consideration on how services promote these types of treatments to patients, bearing in mind the multiple barriers that might discourage treatment acceptance.

ACT model

Our findings show that self-reported symptoms of depression and anxiety are highly correlated with psychological flexibility. This provides support for the ACT model in ESRD and may indicate the possible utility of an ACT-based intervention. In light of our other findings, a non-self-help format (e.g. individual or group psychotherapy) may be more suitable. Outcome studies are needed to examine whether ACT interventions delivered in other formats are acceptable and effective in the ESRD population.

While the need for more research into ACT in ESRD is warranted, our findings offer only limited support for the ACT model. Observational correlational evidence of process-outcome relationships is weaker than proof of principle evidence showing that manipulation of one or more ACT processes is followed by a change in desired outcomes. Furthermore, although depression is the presenting clinical problem, the ACT model does not target or make hypotheses about symptom reduction. As such, we would not necessarily expect increased psychological flexibility to lead to a reduction in depression. Measures indicating increased valued action or quality of life may be a better demonstration of proof of principle.

Our conclusions about process-outcome relationships assume that the AAQ-II is a good proxy measure for psychological flexibility. Using exploratory factor analysis, Wolgast (2014) demonstrated that items on the AAQ-II were more strongly associated with items measuring distress than those measuring experiential avoidance. He concluded that the AAQ-II failed to adequately discriminate between constructs and that this may have led to an overestimation of the relationship between ACT processes and distress. We defend its use here as it remains the most widely used and researched measure of psychological flexibility, however it is important to consider the limitations of the AAQ-II before drawing strong conclusions about the ACT model.

Strengths and limitations¹⁶

The main limitation of the trial is that low recruitment numbers and poor adherence prevented us from drawing conclusions about which aspects of the self-help manual might be most helpful for ESRD patients and precluded further proof of principle exploration of the ACT model. However, the mixed methods approach strengthened

¹⁶ See Extended Discussion 4.4 and 4.5 for further information on strengths and limitations

the design by providing a more detailed account of the practicalities of conducting the research.

Conclusion

Our trial procedures were largely acceptable however low recruitment rates and poor adherence suggest that the intervention was inappropriate for treating depression in ESRD. A combination of factors may account for our low recruitment including the high treatment burden already experienced by dialysis patients, stigmatisation, denial or misattribution of depressive symptoms, disorder specific factors and high morbidity. Supported self-help based on ACT may have a utility in this population but more research is needed to examine where this utility might lie.

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Extended Paper

1. Extended Introduction

This section of the extended paper provides further details on renal replacement therapy and the epidemiology of depression in ESRD. A review of the evidence base for pharmacological and psychotherapeutic interventions for depression in ESRD is provided. This is followed by a more detailed account of the ACT model and the current evidence base, as well as a review of self-help interventions more generally. The section will conclude with a look at the aims and epistemological position of the research.

1.1 Renal replacement therapy

Unless otherwise states, figures included in this section are taken from the UK Renal Registry 18th Annual Report and relate to the 2014 calendar year (MacNeill, Casula, Shaw & Castledine, 2016). The most common form of renal replacement therapy in the UK is kidney transplantation, accounting for 53% of all treatment. The second most common treatment is haemodialysis, in which a vascular connection is made between the patient and an artificial kidney. Patients typically have three, four-hour haemodialysis session per week. Haemodialysis accounts for 41% of all renal replacement with the vast majority of patients receiving haemodialysis at a satellite clinic (50.7%) or main hospital site (40.4%), while a smaller number facilitate their own treatment at home (4.9%). A third option for treatment is peritoneal dialysis in which blood is filtered through the patient's peritoneum, a thin membrane which lines the abdomen. Dialysate solution is passed into the peritoneal cavity at the start of dialysis and drained out after 4-8 hours. Only 6.1% of renal replacement therapy patients receive peritoneal dialysis.

In the UK, the median age of haemodialysis patients (67.2 years) is higher than that of peritoneal dialysis patients (64.2 years) and substantially higher than transplant patients (53.3 years). Sixteen per cent of all renal replacement therapy patients are over the age of 75. ESRD patients experience a high symptom burden. A systematic review found the most common symptoms to be fatigue (71%), pruritus (severe itching; 55%), constipation 53%, anorexia (49%), pain (47%), sleep disturbance (44%), anxiety (38%), dyspnea (trouble breathing; 35%) nausea (33%), restless legs 30%, and depression (27%; Murtagh, Addington-Hall & Higginson, 2007).

1.2 Depression in ESRD

The incidence of depression is perhaps unsurprising given the high number of stressors often experienced by ESRD patients including changes in social, family and occupational role, loss of physical, sexual and cognitive functioning and considerable treatment burden (Bohra & Novak, 2015). There continues to be wide variation regarding the extent of depression in ESRD with estimates ranging from 10 to 47% (Craven, Rodin & Littfeld, 1988; Kimmel, 2001; Kimmel et al., 1995; Kimmel et al., 1998; Kimmel et al., 1996; Lopes et al., 2004; Smith, Hong & Robson, 1985; Watnick, Kirwin, Mahnensith & Concato, 2003). This variation is largely explained by the variety of assessment methods used, with higher estimates generally found when using self-report methods and lower rates using diagnostic interview (Cohen, Norris, Acquaviva, Peterson & Kimmel, 2007). The prevalence of depression may vary by country with the highest rates in the United States and the lowest rates in Japan (Lopes et al., 2004).

Rates of depression seem to vary depending on the mode of renal replacement therapy patients receive with the highest rates found in haemodialysis patients (Martin, Tweed & Metcalfe, 2004). Irrespective of the mode of treatment, the prevalence of depression in ESRD is significantly higher than in the general population where lifetime prevalence estimates for England range from four to ten per cent (McManus, Meltzer, Brugha, Bebbington & Jenkins, 2009), an estimate that is consistent across other European countries (Alonso et al., 2004). Furthermore, rates of depression are greater in ESRD when compared with other chronic physical health problems such as congestive heart failure (Jiang et al., 2001) and diabetes (Anderson, Freedland, Clouse & Lustman, 2001). This has been supported by a large US study in which one-year prevalence rates of depression were three times higher than the general population for ESRD patients compared with two times higher in patients with coronary artery disease, hypertension, heart failure, and diabetes (Egede, 2007).

Although depression appears common in ESRD, diagnostic difficulties arise due to the overlap between the symptoms of depression and those of ESRD, including sleep problems, fatigue, appetite disturbance and cognitive difficulties (Chilcot, Wellsted & Farrington, 2010; Drayer et al., 2006). To diagnose depression in ESRD, it has been argued that attention should be paid to the psychological symptoms of depression, such as hopelessness, low mood and suicidal thinking (Kimmel, 2001). However, research suggests that under-diagnosis is more likely when the physical symptoms of

depression are omitted from assessment and that a more inclusive approach leads to greater consistency in prevalence rates (O'Donnell & Chung, 1997).

As previously discussed, there is a well-established link between depression and a variety of negative health-related outcomes with several mechanisms implicated. These include poor compliance with medication and dialysis (Kaveh & Kimmel, 2001; Kimmel, 2001; Kimmel, 2002), poor nutritional status (Cohen & Kimmel, 2007), and altered immune system functioning (Kimmel, 2001; Miller, Cohen & Herbert, 1999).

1.2.1 Psychopharmacological Treatments

Few studies, and only one randomised controlled trial (RCT), have examined the effectiveness of pharmacological treatments for depression in ESRD. In a double-blinded placebo controlled trial (n=14), Fluoxetine was found to be an effective treatment for depression in patients receiving dialysis, although significant differences in self-reported depressive symptoms did not occur until four weeks into the trial and were not maintained at eight weeks (Blumenfield et al., 1997). The findings of this study are limited by the small sample size and short duration of the trial. The protocol for a high-quality, double blind placebo-controlled pilot RCT examining the effectiveness of Sertraline for haemodialysis patients with depression, was published last year, with the aim of filling this gap in the literature (Friedl et al., 2015). Of greater relevance to the present research is the ASCEND trial, the first large-scale, multi-centre RCT comparing individual chair-side CBT with Sertraline (for the protocol, see Hedayati et al., 2016). At the time of writing, this study is in the recruitment phase and has an estimated completion date of August 2017 (<https://clinicaltrials.gov/ct2/show/NCT02358343>).

1.2.2 Psychotherapeutic Treatments

Only a handful of studies have examined the effectiveness of psychotherapeutic interventions for treating depression in ESRD and fewer still have specifically targeted haemodialysis patients. A 2005 Cochrane review identified no RCTs of psychosocial interventions for depression in dialysis patients and was therefore unable to draw conclusions about the effectiveness of such interventions (Rabindranath et al., 2005). Since then, some trials have been conducted with favourable findings. Given the limited number of trials in ESRD overall, an overview of all known trials, regardless of the type of renal replacement therapy (RRT) received by participants, is provided.

CBT is the most widely researched therapeutic model for the treatment of depression in ESRD. In a recent randomised crossover trial (Cukor et al., 2014), 59 haemodialysis patients were allocated to either individual CBT or waiting-list control. All patients met relevant cut-offs for depression on the Beck Depression Inventory (BDI-II; Beck, Steer, Ball & Ranieri, 1996) and Hamilton Depressive Rating Scale (HDRS; Hamilton, 1960). Patients in the intervention group received individual chair-side CBT during dialysis, administered weekly for three months. Scores on the BDI-II and HDRS significantly improved in the intervention group compared with controls and this was sustained at 3-month follow-up. An uncontrolled pilot study which preceded this trial also found significant and sustained improvements in BDI-II scores for all 16 ESRD patients receiving chairside CBT (Cukor, 2007).

In a Brazilian trial, 85 haemodialysis patients with a diagnosis of major depression were randomised to receive group CBT or standard care (Duarte, Miyazaki, Blay & Sesso, 2009). Depression diagnosis was determined using the Mini International Neuropsychiatric Interview. Those who were randomised to the treatment condition received 12 weekly sessions of group CBT, each lasting 1 hour 30 minutes. The number of patients in each therapy group is not clear. Improvements in BDI-II scores were found in both the control and CBT arms however greater gains in depression and quality of life scores were found for CBT which were maintained at 9-months. Further support for group-delivered CBT as a treatment for depression in ESRD has been reported in a case study of five haemodialysis patients who received two sessions of group therapy (Kaniarz, 1998). These findings however, are extremely limited due to the lack of rigour associated with the case study methodology, in particular the extremely small sample size and lack of control group for comparison.

In an Israeli study, 15 medical centres were randomised to receive supportive psychotherapy, CBT or no-treatment (Hener, Weisenberg & Har-Even, 1996). Participants were individuals adjusting to home peritoneal dialysis and their partners. Couples in the supportive psychotherapy and CBT groups received eight, 80-minute sessions of therapy in their homes. A diagnosis of depression was not required for inclusion in the trial. Interestingly, supportive psychotherapy emphasised acceptance of the illness and encouraged emotional expression, aspects that would be consistent with the ACT model. Significant improvements in depression and anxiety were found for both treatment groups compared with no-treatment controls, although no longer-term follow-up data was collected. There were no significant differences in outcomes between the two types of therapy.

In another randomised trial, individual and group psychotherapy treatments were compared against a non-treatment control group for individuals who had received a kidney transplant (n=126; Baines, Joseph & Jindal, 2004). The same therapeutic model, Systemic Integrative Psychotherapy, was delivered in both the individual and group therapy conditions over twelve weekly sessions. The authors report significant improvements in depression in both conditions when compared with the non-treatment group, although differences appeared more significant in the individual therapy group. Improvements were sustained at twelve-month follow-up however, as effect sizes were not reported, it is not possible to deduce the magnitude of the change.

The recent publication of the iDiD trial protocol, detailing a feasibility study examining a telephone-supported computerised CBT intervention for psychological distress in haemodialysis patients (Hudson et al., 2016), demonstrates further recognition for the need to develop low-intensity psychotherapeutic interventions in ESRD. Results from this trial, combined with our own findings, may help to establish the most appropriate format for delivering self-help treatments to haemodialysis patients.

In summary, while the number of methodologically robust trials remains small, those which are available provide some support for both group and individual psychotherapy for treating depression in ESRD. In haemodialysis, both RCTs conducted to date support the use of CBT, although as single-centre trials they lack greater generalisability. The ASCEND trial described above, may go some way to addressing this issue.

1.3 Provision of psychological services in UK renal care

A number of national care guidelines have acknowledged the importance of psychological support in renal care. NHS service specifications for in-centre haemodialysis recommend that patients have access to psychological services (NHS England, 2016). Similar recommendations are given by the Kidney Health Advisory Group (Loud & Gallagher, 2013) and NICE quality standards for treating adults with CKD (NICE, 2011), both of which recommend timely access to psychological support for all patients with advanced kidney disease. However, there are no recent figures on the availability of psychological services across UK renal units. The most recent data, now 14 years old, indicates a considerable dearth of counsellors and clinical psychologists in renal care (British Renal Society, 2002). Although official figures are

unavailable, most units employ or have access to a clinical psychologist and a network of renal clinical psychologists meet quarterly (E. Coyne, Consultant Clinical Psychologist, personal communication, January 13th 2016).

The National Renal Workforce Planning Group propose a tiered framework for providing psychological support in renal care (British Renal Society, 2002). The framework comprises of three levels covering increasing severity of psychological difficulties, with the bottom level provided by all staff, comprising general support such as information, advice and empathy. The next level, provided by nursing, medical and other qualified members of the multi-disciplinary team, involves supportive counselling with a focus on the emotional consequences of receiving illness- and treatment-related information. The final level is psychological assessment and intervention in relation to mental health needs, adjustment, adaptation, coping and the impact of ESRD on the family system. This level should be provided by specialist psychological practitioners including clinical psychologists, counsellors and psychotherapists. Consistent with this tiered approach to psychological support, NICE guidelines for the treatment of depression in chronic physical health problems recommend a stepped-care model in which the least intrusive and most effective treatment is provided first (NICE, 2009). They propose four steps of care with patients receiving increasingly invasive treatments according to need, or as lower steps prove ineffective. Although the tiered framework proposed by the British Renal Society does not correspond with the steps proposed in the NICE stepped-care model, there is recognition from both organisations that both low- and high-intensity psychological interventions are needed within the renal context.

1.4 Acceptance and Commitment Therapy (ACT)

ACT is considered part of the third-wave of behavioural therapies where traditional behavioural therapy is the first wave and CBT is the second wave (Hayes, 2004). It is based on a philosophy of science called functional contextualism, where truth is held to be successful working (Hayes, 1993). The epistemological basis of functional contextualism is discussed in greater depth below.

Fundamentally, ACT is based on the contextual behavioural principles of Skinner (1938; 1948), a full account of which is beyond the scope of this paper but a brief explanation may provide some context for understanding the ACT model. To understand human behaviour from a contextual behavioural perspective we must

consider not only the behaviour itself, but the context in which the behaviour is performed, as well as the consequences of performing it (Törneke & Romero, 2008). As such, a behavioural understanding consists of a three term contingency where A is the antecedent, B is the behaviour and C is the consequences (Törneke, Luciano & Valdivia, 2008). Certain consequences increase the likelihood of a behaviour being performed in a similar context in the future (reinforcement) and other consequences decrease this likelihood (punishment). In this way, behaviour is governed by its consequences and this is known as operant conditioning. As a straightforward example, in the presence of an anxiety-provoking meeting (A), leaving the meeting early (B) leads to a reduction in anxiety (C). This behaviour has been reinforced by its consequences and is more likely to be performed again in similar circumstances in the future.

The ACT model augments the principles of behavioural theory by incorporating a behavioural account of human language and cognition called Relational Frame Theory (RFT; Hayes, Barnes-Holmes & Roche, 2001). Again, a full account of the assumptions and theory of RFT is beyond the scope of this paper but a brief account is provided. According to RFT, language and cognition is based on the learned ability to arbitrarily relate events. Through multiple exemplar training in early childhood, humans learn to relate stimuli that have no relation in their learning history, even when the stimuli have no formal properties in common (Törneke, 2010). This is known as derived relational responding. This ability to relate is reinforced through the operant processes described above and generalises to other stimuli (Healy, Barnes-Holmes & Smeets, 2000). These arbitrarily established relations result in a transformation of stimulus functions (the response evoked by a stimulus) whereby the function of one stimulus acquires the function of the other by virtue of this arbitrary relationship. To explain this premise, Törneke et al. (2008) use the example of being told that a number of local people have contracted typhoid, a disease spread through badly prepared chicken. As a result, eating chicken is placed in a relational frame of coordination with feeling sick and its stimulus functions are transformed (i.e. chicken elicits a sick feeling). RFT specifies a number of ways in which the functions of language lead to psychological distress and it is these processes that are targeted in ACT. A review of the empirical basis for RFT found 62 empirical studies and concluded that there was a growing evidence base supporting the main assumptions of RFT (Dymond, May, Munnally & Hoon, 2010).

At the heart of ACT is the concept of destructive normality wherein psychological pain is universal and the product of normal processes of human language and cognition, as

specified in RFT (Hayes, Strosahl & Wilson, 1999). The verbal processes implicated in psychological distress are some of the same processes that are involved in verbal reasoning and problem solving and so attempts to eliminate these processes will be inherently problematic (Hayes, Luoma, Bond, Masuda & Lillis, 2006). The assumption of destructive normality separates ACT from other therapeutic traditions, including CBT, where the central assumption is one of healthy normality. By this account, humans naturally function in a state of good psychological health, characterised by happiness and contentedness. Psychological pain is a deviation from this normal state and is driven by abnormal, pathological processes inside the client (e.g. maladaptive cognitive patterns). While CBT and other psychotherapies aim to eliminate or reduce psychological pain, ACT asserts that attempts to control or avoid pain may lead to additional suffering and that the elimination of pain is not necessary to live a valued and meaningful life. ACT theorists cite the high prevalence rates of common mental health problems as convincing evidence to support the destructive normality hypothesis. This is perhaps especially relevant in populations such as ESRD patients, where there are particularly high rates of psychological distress. With prevalence rates of depression ranging from 20 to 40% in the ESRD population (e.g. Chilcott et al., 2010) it is difficult to argue that psychological pain represents a deviation from normality.

1.4.1 ACT model

Underlying the ACT model is the concept of *psychological flexibility*, the ability to consciously connect with the present moment and respond flexibly in the service of one's values (Hayes et al., 1999). The aim in ACT is to increase psychological flexibility by targeting six core repertoire-expanding processes, each of which corresponds with a repertoire-narrowing process. The latter set of processes arises from characteristics of human language and cognition (Hayes et al., 1999).

1.4.2 Acceptance vs. experiential avoidance

Acceptance involves increasing an individual's willingness to accept private events such as thoughts, memories, emotions and bodily sensations, even when they are distressing or aversive (Hayes et al., 1999). It is not a resigned, passive acceptance of these experiences but an active, curious and deliberate exploration of them (Hayes, Pistorello & Levin, 2012). The repertoire-narrowing counter to acceptance, experiential avoidance, involves attempts to alter the form or frequency of unwanted private experiences (Hayes, Wilson, Gifford, Follette & Strosahl, 1996). Such attempts often

result in a narrowing of the individual's behavioural repertoire as they struggle to avoid these private events. In part, experiential avoidance is problematic due to the extension of relational networks. While non-humans can avoid situations that illicit pain and distress, the functions of language are such that humans can experience pain at any time, wherever they are (Törneke & Ramnero, 2008).

The aim of acceptance is to increase one's ability to respond flexibly to private experiences. A relationship has been found between experiential avoidance and a number of negative mental health outcomes, including depression and anxiety (Hayes et al., 2006). In order to foster acceptance, the therapist helps the client to see the futility and counter-productiveness of control and avoidance strategies. To achieve this, the therapist helps to produce a sense of *creative hopelessness* in which the cost of control and avoidance strategies, increased suffering and a failure to move towards identified values and goals, is highlighted. The client is then encouraged to abandon these strategies and accept private experiences in the pursuit of their values. Acceptance is not a goal in itself but a means of bringing about value-guided action (Hayes et al., 2012).

1.4.3 Cognitive defusion vs. cognitive fusion

Cognitive fusion is a process which occurs when thoughts take on a literal quality, acquiring the stimulus functions of what they refer to (Hayes et al., 2006). Individuals will respond to these cognitions in a way that is similar to how they would respond if the tangible properties of the event represented in the cognition were present. For example, an individual who is having thoughts about a medical procedure going wrong may experience fear or anxiety even though they are not having a medical procedure at the present moment. In ACT, this process is targeted through cognitive defusion which centres on changing the way individuals interact with their thoughts and other private experiences (Hayes et al., 2012). Rather than attempting to change the form or frequency of these experiences, defusion strategies aim to alter their undesirable functions by creating a context in which these functions are diminished (Hayes et al., 2006). When fused with thoughts, they play an excessive role in regulating behaviour, leading to inflexible patterns of responding. The role of defusion is to help clients to see their thoughts, not as literal truths, but psychological events that can be responded to flexibly (Hayes et al., 2006). A wide variety of techniques have been developed to help clients to defuse from their thoughts, including encouraging them to visualise their thoughts floating past on a cloud, speaking their thoughts repeatedly or in an amusing

voice, or labelling the thought as a thought (e.g. “I am having the thought that...”; Hayes & Strosahl, 2005).

1.4.4 Contact with the present moment vs. domination of the past or future

To use cognitive defusion effectively, a degree of present moment awareness is needed as this allows the process of thinking to become more evident (Hayes et al., 2012). This present moment awareness, known as mindfulness, allows individuals to make contact with psychological and environmental events as they occur, viewing them with curiosity and without judgement (Hayes et al., 1999). Mindfulness is also an essential part of acceptance as one must have an open awareness of events in the present moment, in order to accept them. By taking notice of internal and external events in the present moment, the individual is able to respond flexibly and in a way that is more consistent with their values. Mindfulness aims to reduce a rigid attention to past and future experiences (Hayes et al., 2012). For example, one might dwell on past losses or worry about future demands, while ignoring what is occurring in the present. This again is a function of language (Törneke & Ramnero, 2008). Mindfulness is developed through activities and techniques which encourage an ongoing description of private events. This might involve paying attention to different parts of the body in turn, attending to the breath or simply noticing the sounds in the room. The therapist also encourages the client to notice what thoughts, memories, emotions and sensations arise within the therapeutic relationship (Wilson & Dufrene, 2009).

1.4.5 Self as context vs. self as content

A product of relational framing is that certain frames lead us to experience ourselves as if we are our thoughts, memories, emotions and sensations, rather than an observer of these experiences (Hayes et al., 2006). We typically describe ourselves as if we are these psychological events and this creates a self-narrative or conceptualised self, which can limit behavioural flexibility (Hayes et al., 2012). This reduced response flexibility occurs because individuals are reluctant to engage in behaviour that deviates from the conceptualised self and this leads to increased experiential avoidance (Mendolia & Baker, 2008). In ACT, this is known as self as content. The therapeutic process aimed at targeting this is called self as context and involves helping individuals to see the distinction between the thinking self (self as content) and the observing self (self as context; Harris, 2009). Mindfulness is often central to this process as it encourages individuals to experience private events as an observer without being caught up in judgements or attempts to alter them. Self as context helps to foster

acceptance and defusion as it gives individuals a safe space to notice their experiences without attachment (Hayes et al., 2006). Self as context interventions also involve metaphors such as the chess board metaphor (Hayes et al., 1999). In this metaphor, self as content equates to viewing oneself as the chess pieces moving around the board, while self as context equates to viewing oneself as the chessboard upon which private events (the chess pieces) occur.

1.4.6 Values clarification vs. unclear and avoidant motives

As previously described, the ultimate aim of ACT is to increase value-consistent behaviour. Unlike goals, values cannot be obtained or reached; instead they are qualities of purposive action (Hayes et al., 1999). For example, looking after one's health is not an outcome that can be achieved, but a continuous process that may extend throughout the lifespan. Often, attempts to avoid or control unwanted private experiences result in moving the individual away from what they most value. By supporting individuals to clarify what is most important to them, it is possible to link values with behaviour change while highlighting the cost of continued avoidance, in terms of distancing the individual from their values. From an RFT perspective, values are verbally constructed contingencies which create an intrinsic reinforcement for patterns of behaviour which are consistent with identified values (Wilson, Sandoz, Kitchens & Roberts, 2010). Values clarification is achieved through metaphor, experiential processes and writing exercises (Hayes et al., 2006).

1.4.7 Committed action vs. unworkable solutions

Closely linked with values clarification is the process of committed action where the aim is to create an ever increasing behavioural repertoire linked to chosen values (Hayes et al., 2006). Consistent with first- and second-wave behavioural therapies, committed action usually involves a graded approach to behavioural change guided by short, medium and long-term goals (Hayes et al., 2012). In ACT, these goals are informed by the individual's values but unlike values, they are obtainable behavioural outcomes. Acceptance, mindfulness and defusion skills allow the individual to manage the psychological barriers which inevitably arise during attempts at value-guided action (Hayes et al., 2006). Committed action stands in contrast to the unworkable solutions that arise through experiential avoidance.

1.4.8 ACT evidence base

A number of meta-analyses and narrative reviews of the ACT evidence base have now been conducted. Most recently, a meta-analysis examining ACT interventions for depression, anxiety, addiction and somatic health problems found ACT to be superior to psychological placebo, wait-list and treatment as usual on primary (Hedge's $g = .57$), secondary ($g = .30$) and process outcome measures ($g = .56$), while no significant differences between ACT and CBT, the established treatment, were found (A-Tjak, et al., 2015). Contrary to this, an earlier meta-analysis found mean effect sizes favouring ACT over CBT for depression (Hedge's $g = .27$) and quality of life ($g = .25$) post-treatment (Ruiz, 2012). The author carried out a further analysis of nine studies that had conducted mediational analyses examining processes of change, reporting that while ACT operated through its proposed processes, CBT did not.

In another meta-analysis, ACT outperformed control conditions (psychological placebo, treatment as usual and wait-list) for target problems overall at post-treatment and follow-up, but failed to outperform established treatments (Powers, Zum Vörde Sive Vörding & Emmelkamp, 2009). Contesting these findings, Levin and Hayes (2009) re-analysed studies in the previous authors' database and found an effect size favouring ACT over established treatments (Hedge's $g = .27$). Two narrative reviews also report broad support for ACT in a variety of clinical problems (Hayes et al., 2006; Smout, Hayes, Atkins, Klausen & Duguid, 2012).

A less favourable review examining ACT for a range of clinical problems found a small overall effect size ($r = .42$) and concluded that ACT failed to fulfil the criteria for an empirically supported treatment, although the best evidence was for chronic pain and tinnitus (Öst, 2014). This was consistent with an earlier review by the same author (Öst, 2008). In both reviews, the methodological quality of ACT RCTs was inferior to those examining CBT, although the procedure for matching ACT and CBT trials in order to examine their respective methodological quality has been questioned (Gaudiano, 2009). The areas of methodological quality in which ACT was consistently inferior to CBT trials were: representativeness of the sample, reliability of the diagnosis, reliability and validity of outcome measures, assignment to treatments, number of therapists administering the interventions, therapist training and experience, checks for treatment adherence, control of concomitant treatments, statistical analyses and presentation of data, clinical significance, and equality of therapy hours between conditions (Öst, 2008).

Alongside outcome research, a number of studies have examined the therapeutic processes underpinning the ACT model. Much of this research involves correlational analyses examining the relationship between experiential avoidance and psychological distress. Typically, experiential avoidance is measured using the AAQ-II or its predecessor, the AAQ (Hayes et al., 2004). Some problem specific adaptations of this measure, such as the Chronic Pain Acceptance Questionnaire (CPAQ; McCracken, Vowles & Eccleston, 2004), have also been developed. A review of the correlational data found a strong weighted correlation between depressive symptoms and experiential avoidance ($r = .55$), based on 22 correlations (Ruiz, 2010). A similarly strong weighted correlation was found between anxiety symptoms and experiential avoidance ($r = .52$), based on 14 correlations. A meta-analysis by Hayes et al. (2006) reported similar positive correlations between experiential avoidance and the majority of psychological symptoms while negative correlations were found between experiential avoidance and quality of life. The authors also found that experiential avoidance, as measured by the AAQ, explained 16 to 28% of the variance in health-related outcomes.

If one assumes that measures such as the AAQ-II are good proxy measures for experiential avoidance, then these reviews provide strong support for the ACT model of psychopathology and treatment. However, both the AAQ and AAQ-II have received criticism, the former for its lack of comprehensibility and reliability (Bond et al., 2011) and the latter for its inability to discriminate between constructs. Wolgast (2014) used exploratory factor analysis to investigate the extent to which the AAQ-II could discriminate between experiential avoidance and psychological wellbeing, finding that items on the AAQ-II were more strongly associated with items measuring distress than those measuring experiential avoidance. These findings indicate that there may be an overestimation of the association between experiential avoidance and distress, particularly in light of the wide proliferation of the AAQ-II. However, at present it remains the most widely used and researched ACT process measure

Overall, there is a mixed picture of the ACT evidence base although in general, ACT was equivalent to established treatments and better than placebo conditions for a range of mental health problems. Where researchers have argued that the evidence does not support ACT as an empirically supported treatment, this is largely due to unsatisfactory research methodology and clearly there is a need for more large-scale, high-quality RCTs. It appears that the theoretical orientation of the researchers is a factor when considering the efficacy of ACT with the most favourable reviews having

been conducted by proponents of the ACT model. Correlational data supports the ACT model of psychopathology although better measures of ACT processes may need to be developed to draw stronger conclusions.

1.4.9 Acceptance in CKD

While there remains a dearth of research examining the potential benefits of psychotherapeutic interventions in ESRD, the impact of psychosocial factors has garnered significant attention. A small proportion of this attention has been on the concept of acceptance with some authors recommending the provision of treatments that foster acceptance in CKD patients in order to bring about positive health outcomes (Chan, 2013; Chiang, Livneh, Guo, Yen & Tsai, 2015). This section of the extended paper will give an overview of the concept of acceptance and its potential significance in the course of CKD.

Acceptance was first conceptualised as the final stage in a five-stage model of grief, where denial, anger, bargaining and depression make up the preceding stages (Kubler-Ross, 1969). Within this framework, acceptance is viewed as an adaptive state which allows individuals to acknowledge and be at peace with the reality of their situation. Over-reliance on denial strategies and failure to achieve acceptance is seen as pathological. Initially derived from work with terminally ill patients and later applied to people with Acquired Immune Deficiency Syndrome (AIDS; Kubler-Ross, 1987), the model has since been used as a general framework for considering adaptation to chronic illness. However, despite its wide application, the model has received considerable criticism, mainly for its prescriptive account of grief and the adaptational process (e.g. Corr, 1993).

It has been argued that there may be two distinguishable types of acceptance in chronic illness and that these may lead to different health outcomes (Nakamura & Orth, 2005). Resigned acceptance involves a recognition and awareness of the negative experiences associated with one's illness, accompanied by passive behaviour and stoical tolerance. This type of acceptance is related to poorer outcomes in a variety of chronic illnesses including breast cancer (Greer, Morris, Pettingale & Haybittle, 1990; Pettingale, Morris, Greer & Haybittle, 1985) and AIDS (Reed, Kemeny & Taylor, 1994). Conversely, active acceptance comprises two processes; the recognition of negative experiences without engaging in self-defeating behaviours intended to control said experiences; and the assimilation of the illness into one's life while pursuing values and

goals (Chan, 2013). Active acceptance has been shown to be positively associated with psychological well-being in an array of chronic health problems including coronary artery disease and cancer (Karademas, Tsagaraki & Lambrou, 2009), chronic pain (McCracken & Zhao-O'Brien, 2010), diabetes (Richardson, Adner & Nordstrom, 2001), chronic fatigue syndrome (Van Damme, Crombez, Van Houdenhove, Mariman & Michielsen, 2006), and rheumatoid arthritis (Persson, Berglund & Sahlberg, 1996). The concept of active acceptance is consistent with the ACT conceptualisation of acceptance.

Given the prominence of acceptance in the grief literature, it is perhaps unsurprising that many studies have adopted the loss-oriented Acceptance of Disability Scale (ADS; Lindowski, 1971) or its successor, the Acceptance of Disability Scale – Revised (ADS-R; Groomes & Linkowski, 2007), in order to examine acceptance in chronic conditions. Acceptance of disability is seen as a coping task that is central to psychosocial adjustment to chronic illness (Groomes & Linkowski, 2007). Individuals must acknowledge and actively accept the impact and chronic nature of the disease before they are able to perform adaptive behaviours (Chan, 2013). The relationship between acceptance of disability and positive health outcomes has been demonstrated in CKD. In a three-year prospective cohort study of 262 CKD patients, acceptance of disability was negatively related to an increased risk of poor clinical outcomes with those who scored lower on the AOD-R more likely to have progressed to dialysis or died at follow-up (Chiang et al., 2015).

Further evidence has highlighted the clinical significance of acceptance in CKD. In a qualitative study using semi-structured interviews and Grounded Theory, Wright and Kirby (1999) explored patients', partners' and professionals' conceptualisations of adjustment to ESRD. They identified acceptance, consisting of cognitive, behavioural and affective components, as the key factor in psychosocial adjustment to the disease. More recently, a cross-sectional study examined the direct and mediating effects of acceptance and personality characteristics on health-related quality of life in patients with CKD (Poppe, Crombez, Hanouille, Vogelaers & Petrovic, 2013). The authors report a small direct effect of acceptance on physical health ($r^2 = .18$) and a medium direct effect on mental health ($r^2 = .31$). They conclude by recommending that future research is needed to examine which psychological interventions can foster acceptance in patients with ESRD.

1.5 Self-help treatments

Self-help is defined as a self-administered treatment which utilises manuals or books which are based on an evidence-based intervention (NICE, 2004). Self-help interventions can be both guided and unguided. Guidance typically involves supporting individuals to move from a position of passivity to one of therapeutic engagement, while helping them to actively engage with and understand the self-help materials.

An increasing number of studies have demonstrated the efficacy of self-help interventions for treating common mental health problems with some studies finding effect sizes comparable with face-to-face therapy. For example, in one meta-analysis, there was no significant difference in effect size between guided self-help and face-to-face therapy for anxiety and depression, post-intervention or at follow-up (Cuijpers, Donker, van Straten & Andersson, 2010). Self-help has also been used successfully in the treatment of psychological distress for people with long-term physical health problems. A meta-analysis which included 25 studies found a small but significant effect favouring written self-help over control conditions for reducing symptoms of depression in individuals with physical illness ($SMD = -0.13$; Matcham et al., 2014). No significant differences were found between self-help and control conditions for anxiety or psychological distress. The analysis included both guided and unguided self-help interventions but only eight were based on a therapeutic model. Effect sizes were larger when studies with interventions not based on therapeutic models were excluded ($SMD = -0.37$). This suggests that self-help treatments are most effective in physical conditions when they are derived from an evidence-based therapeutic approach.

To date, there have been no trials examining the efficacy of self-help interventions in ESRD however ACT self-help has received some attention. A meta-analysis examining the efficacy of acceptance and mindfulness-based self-help interventions, which included seven ACT studies, found significant increases in mindfulness and acceptance, and reductions in anxiety and depression, when compared with control conditions (Cavanagh, Strauss, Forder & Jones, 2014). Small to medium effect sizes were reported. The majority of studies included self-help interventions with some form of guidance although this varied considerably in terms of format and time with some protocols only providing email-based guidance.

Meta-analytic studies have shown that self-help treatments are ineffective at treating depression and anxiety when no additional therapeutic guidance is provided (Gellatly et

al, 2007; Hirai & Clum, 2006) although others meta-analyses have been more favourable (e.g. Cuijpers et al., 2010). This suggests that self-help materials may need to be supplemented with guidance from a practitioner in order for them to produce meaningful outcomes. The importance of guidance in self-help interventions may be related to the therapeutic alliance. Bordin's (1979) widely recognised conceptualisation of the therapeutic alliance comprises three essential elements. The first element regards the mutually agreed goals of therapy. The second element, the therapeutic bond, refers to the positive affective connection between client and practitioner, and the third element, the therapeutic tasks, refers to the mutually agreed means of achieving the therapeutic goals.

The powerful effect of the therapeutic alliance on treatment outcomes is well-established in psychotherapy research (Ardito & Rabillino, 2011) with some evidence to suggest that it may be the most significant mechanism of change across therapeutic orientations (e.g. Fluckiger Del Re, Wampold, Symonds & Horvath, 2012). Strong positive correlations have been reported between therapeutic alliance and outcome regardless of the therapeutic model, assessment tool used or time of assessment (e.g. Horvath, Del Re, Fluckiger & Symonds, 2011). The role of the therapeutic alliance in guided self-help interventions has been examined in both quantitative and qualitative research. Coull and Morris (2011) found that the therapeutic alliance predicted improvements in mental health for individuals who completed a CBT-based guided self-help intervention for depression and anxiety. Furthermore, in a meta-synthesis of nine qualitative studies examining guided self-help, Khan, Bower and Rogers (2007) found that an effective therapeutic alliance positively impacted on individuals' use of self-help. These studies highlight the potential importance of the therapeutic alliance in terms of self-help utilisation and outcomes.

1.5.1 Rationale for ACT self-help in renal services

There is a strong rationale for providing an ACT-based self-help intervention to haemodialysis patients experiencing depression. This rationale is based on the following:

1. Self-help allows increased access and availability of an evidence-based intervention for a population where there is a high prevalence of psychological distress and where access to psychological interventions may be limited.
2. Self-help has the potential to extend the provision of evidence-based

psychotherapeutic interventions to individuals who might not access traditional face-to-face psychological therapy (e.g. due to stigma).

3. The provision of low-intensity interventions is consistent with a stepped model of care as recommended in NICE guidance for the treatment of depression in long-term conditions (NICE, 2009).
4. Guided self-help may be a cost-effective means of providing an evidence-based intervention to large numbers of people with minimal practitioner input.
5. Supporting the self-management of health-care needs is recommended in NICE guidance for the assessment and management of CKD. Self-help is consistent with a self-management model of care and might help to foster a sense of empowerment, self-efficacy and autonomy.
6. The self-help materials remain in the possession of the client allowing them to update or renew their treatment as often as they require.
7. Haemodialysis patients endure a considerable treatment burden. Self-help allows individuals to access an evidence-based intervention with flexibility and convenience without additional healthcare appointments.
8. There is promising evidence for the efficacy of ACT-based self-help treatments for depression and other conditions, as well as some evidence linking ACT processes to positive mental and physical health-related outcomes.
9. Self-help has been used effectively to treat depression in other long-term physical health problems.

1.6 Feasibility randomised controlled trials

The Medical Research Council (MRC) recommends the use of feasibility and pilot studies as an essential preparatory stage in the development and evaluation of complex interventions (Craig et al., 2008). The purpose of feasibility and pilot studies is to allow potential problems to be identified before carrying out a definitive trial. The MRC cite common problems that arise in evaluation studies relating to acceptability, compliance, intervention delivery, recruitment and retention. The National Institute of Health Research (NIHR) Evaluation, Trials and Studies Coordinating Centre (NETSCC) provide clear definitions to help researchers differentiate between feasibility and pilot studies (<http://www.nets.nihr.ac.uk/glossary>). Feasibility trials are used to determine important parameters that are needed to design a definitive trial. These parameters may include: number of eligible patients, response rates, follow-up rates, adherence rates and willingness of facilitating clinicians to recruit participants. Pilot studies

Table 9

Feasibility parameters

Parameter	Operationalisation	Assessed
Screening questionnaire response rate	Proportion of screening questionnaires returned	Frequency and percentage
Rate of depression	Proportion of screened patients who meet cut-off on PHQ-9	Frequency and percentage
Eligibility rate	Proportion of screened patients who meet all eligibility criteria	Frequency and percentage
Recruitment rate	Proportion of eligible patients randomised to trial	Frequency and percentage
Retention	Proportion of participants who remain in the trial at follow-up	Frequency and percentage
Adherence to self-help book	Proportion of participants who complete all chapters of the book and number of chapters completed per participant	Frequency and percentage (weekly adherence recorded during telephone support calls)
Adherence to telephone support	Proportion of telephone calls taking place	Frequency and percentage
Acceptability of recruitment procedure	Participants perceptions of the recruitment procedure	Framework analysis
Acceptability of assessment methods	Participants perceptions of the assessment methods and proportion of items completed per questionnaire	Framework analysis Percentage of completed items/missing data per questionnaire
Acceptability of randomisation procedure	Participants perceptions of the randomisation procedure	Framework analysis
Acceptability of self-help book	Participants perceptions of the self-help book	Framework analysis
Acceptability of telephone support	Participants perceptions of the telephone support	Framework analysis

however, are designed to be smaller versions of the definitive trial and aim to determine whether all aspects of the procedure work together. Table 9 shows the parameters of interest for the present trial, with details of how each of these parameters is operationalised and assessed.

There is a good rationale for evaluating a telephone-supported ACT self-help intervention for haemodialysis patients who experience depression. As such, a feasibility trial is needed in order to estimate relevant parameters for a full-scale trial and to determine whether such a trial is warranted.

1.7 Aims

As a feasibility trial, the present study aimed to determine the acceptability of our recruitment methods, randomisation procedure, assessment methods, self-help materials and telephone support. We also aimed to provide estimates on the number of eligible patients and rates of recruitment, retention and adherence. Two secondary aims were not related to aspects of feasibility. Firstly, we aimed to use individual level analyses to provide provisional data on the potential efficacy of a telephone-supported ACT self-help intervention with this client group. Secondly, we aimed to examine the relationship between experiential avoidance and psychological distress to examine the rationale for using the ACT model with this population.

1.8 Epistemological position

In carrying out the present research we adopted a post-positivist stance. Post-positivism is an extension of positivism, the belief that an objective reality exists independent of human perception, which can be observed, measured and understood through empirical methods (Everest, 2014). While maintaining the central premise that an objective reality exists, post-positivism acknowledges that the researcher cannot be entirely independent of the research and therefore only an approximate understanding of reality can be achieved, based upon the subjective observations and interpretations of the researcher (Denzin & Lincoln, 2000). By this account, truth equates to a correspondence between theory and reality, as much as this is possible, given the limitations created by researcher bias.

As previously described, ACT is embedded in a pragmatic philosophy of science called functional contextualism. In pragmatism, all knowledge is relative and so an absolute truth does not exist (James, 1907). Knowledge refers to the “act in context”, or in other words, behavioural relations as a function of their current and historical setting (Hayes, 1993). An evaluation of truth is itself an act in context and thus, one can never step outside of the behavioural stream to make an objective observation of it (Morris, 1988). By this contextualist account, the criterion of truth is one of successful working rather than correspondence between a model and ontological reality (Hayes et al., 2012).

Post-positivism and functional contextualism both embrace experimental methodology but with different objectives in mind. While post-positivism aims to model reality through experimental procedures (while acknowledging the impact of researcher bias), functional contextualism uses these procedures as a means of realising the goals of the researcher, namely to predict and influence events (Vilardaga, Hayes & Schelin, 2007). The justification for our post-positivist stance is that it remains the dominant paradigm for research examining best practice in psychotherapy (Field, 2012). In accordance with this position, attempts were made throughout the research to ensure researcher bias was reduced as much as was practicable.

2. Extended Methods

This section provides further details on the recruitment procedure, the assessment measures used, the target sample size and the randomisation process. Details of the individual level analysis are also provided as well as a break-down of the self-help manual. Finally, an account of the ethics committee application process is described.

2.1 Recruitment

Four dialysis units, all coordinated by the same NHS Trust, were selected for recruitment. It was hoped that by recruiting from multiple dialysis units this would provide a large enough population from which to identify eligible and interested participants. This also gave us a more representative sample than if recruiting from one unit alone and allowed us to determine the variability in screening questionnaire return rates between different facilitating staff teams.

We utilised two recruitment procedures allowing us to evaluate different approaches to recruitment. In the first procedure, a designated member of staff at each unit was identified to approach participants, provide them with a participant information sheet and determine their interest in participating in the trial. WV was on hand to speak to patients who expressed an interest or wanted more information. This recruitment method was trialled at one dialysis unit but proved extremely time consuming, identifying only two participants who were willing and eligible to participate in the trial. As a result, it was agreed that an alternative recruitment procedure should be pursued in which all haemodialysis patients were screened. WV was then able to approach those who met the cut-off on the PHQ-9 to determine their interest and eligibility. This second recruitment procedure also allowed us to determine the number of patients who met the PHQ-9 cut-off and compare this with previous population estimates for depression.

2.2 Sample Size

For pilot and feasibility trials, a sample size of 24 (12 per arm) has been recommended (Julious, 2005). The rationale for this guidance is based upon recruitment feasibility and precision about the mean and variance of each group. Based upon this guidance and the time-constraints of the research, there was a target sample size of 30 (15 per group) allowing for 25% attrition. Although this attrition rate appears high, in an RCT of a telephone-supported ACT self-help intervention for chronic pain, similar to the

present trial in terms of length, participant burden and intervention, 42% attrition was reported (Johnston, Foster, Shennan, Starkey & Johnson, 2010). However, this high level of attrition appears quite rare with one review finding that in 71 trials only 18% reported a drop-out rate of 20% or more (Wood, White & Thompson, 2004).

2.3 Measures

This section provides additional details on the screening and outcome measures used within the study. As previously described, the Generalised Anxiety Disorder 7-item (GAD-7: Spitzer, Kroenke, Williams & Löwe 2006) scale was included alongside the Patient Health Questionnaire (PHQ-9: Kroenke, Spitzer & Williams, 2001) to examine correlations between psychological flexibility and anxiety at screening. As with the PHQ-9, respondents indicate, using a four-point Likert scale (0 is not at all to 3 is nearly every day) how often they have been bothered by a series of anxiety symptoms over the previous two weeks. The total score is the sum of all items. The GAD-7 is recommended by NICE (2011) and was selected for the present study based on its brevity and excellent reliability (Cronbach's $\alpha = .92$; Spitzer et al., 2006).

The use of the Emotion Thermometer (ET: Mitchell, Baker-Glenn, Granger & Symonds, 2010) at screening allowed us to examine the acceptability of a second distress measure as part of our feasibility analysis. The ET offers a rapid completion time and simplicity. To complete the ET, respondents rate how much emotional upset they have experienced on each domain and the degree to which this has impacted upon them over the previous two weeks. Permission to use this measure was granted by the author. The ET has been validated for use in cancer (e.g. Schubart, Mitchell, Dietrich & Gusani, 2015), epilepsy (Rampling et al., 2012) and cardiovascular disease (Mitchell et al., 2012), although it has yet to be validated with a haemodialysis population. In a sample of cancer patients, the ET showed excellent internal consistency (Cronbach's $\alpha = .91$; Mitchell & Symonds, 2010).

The EQ-5D-5L (EuroQol Group, 1990) assesses five dimensions (mobility, self-care, usual activities, pain/discomfort and anxiety/depression) representing different aspects of the respondents' health state. For each dimension respondents indicate by ticking a box, which of five statements best describes their health today. Each statement represents a different level of perceived problem and corresponds with a number from 1 (no problem) to 5 (extreme problem). These numbers have no arithmetic properties, instead they are combined to create a 5-digit code describing the respondent's overall

health state. A total of 3125 health states are possible. Health states can be converted into a country-specific index value allowing for the calculation of quality-adjusted life years (QALY), a measure of disease burden which is used to determine the cost-utility of an intervention. Scores range from -1 to 1. The EQ-5D-5L has shown acceptable test-retest reliability (intraclass correlation =.69; Janssen et al., 2012)

The Acceptance and Action Questionnaire (AAQ-II: Bond et al., 2011) was also administered as part of the screening procedure to enable inferences to be drawn about those who wish to participate and those who do not, and to examine the relationship between psychological flexibility and distress. Respondents rate how much they agree with seven statements using a seven point Likert scale where 1 is *never true* and 7 is *always true*. The measure is scored by totalling the answers, with possible scores ranging from 7 to 49. High scores indicate greater psychological inflexibility. Internal reliability of the AAQ-II is good (Cronbach's α =.84).

The Valued Living Questionnaire (VLQ: Wilson et al., 2010) was used as a functional measure to provide preliminary analysis of whether the intervention fosters valued action. For each domain the importance score and consistency score are summed and the mean is calculated. The mean scores for all domains are then summed to provide a valued-living composite score. Preliminary analysis indicates that the VLQ composite score has good internal consistency (Cronbach's α =.7) and test re-test reliability (intraclass correlation =.75).

2.4 Randomisation and blinding

An account of the randomisation procedure can be seen in the journal paper above. Given the nature of the trial, blinding was not possible. It was necessary to inform participants of their allocation in order for those allocated to the intervention arm to be provided with the self-help manual. WV was aware of allocation as he informed participants which group they had been allocated to and provided telephone support to those allocated to the self-help arm of the trial. WV was not aware of the computer-generated random number sequence used in the randomisation procedure. The interviewer (BP) was also aware of allocation as participants in the intervention arm were given more questions to answer than those in the treatment as usual arm.

Table 10

Overview of weekly reading, chapter titles and contents in Hayes and Smith (2005)

Week	Chapter title	Content of chapters and processes targeted
1	Introduction	General introduction to ACT model and processes.
	Chapter 1: Human suffering	Introduces notion of destructive normality and the process of experiential avoidance. Exercises help readers generate a suffering inventory and consider how their life would be different if they were not struggling with pain. These exercises lay the groundwork for creative hopelessness.
	Chapter 2: Why language leads to suffering	Introduces RFT principles using exercises and a series of figures depicting how a relational network with two trained relationships expands to six relationships with no further training (i.e. four relationships are derived). Creative hopelessness is built using an exercise in which readers identify their coping strategies and rate the long and short-term success of these strategies. Exercises and metaphor are used to demonstrate ineffectiveness of avoidance. The relationship between language and experiential avoidance is explained. A metaphor is used to introduce the difference between cognitive fusion and defusion.
2	Chapter 3: The pull of avoidance	Uses several metaphors and an example to explain the ineffectiveness and futility of the control/avoidance agenda. Discusses various reasons why we have learnt to pursue this agenda. An exercise is used to help readers evaluate the workability of their control strategies over a number of days. Another exercise acts as a primer for mindfulness by asking readers to record present moment thoughts and feelings.
	Chapter 4: Letting go	Introduces acceptance as an alternative to experiential avoidance. Several metaphors are used to exemplify this. Research is cited to emphasise the importance of acceptance in different clinical problems. Exercises are used to show the advantages of acceptance.
	Chapter 5: The trouble with thoughts	Discusses thought production, cognitive fusion and the relationship between cognitive fusion and experiential avoidance. Exercises are used to help readers to reflect on their thoughts and to determine which thoughts are most related to their struggle with pain. An exercise is also used to demonstrate the difference between fusion and defusion.
3	Chapter 6: Having a thought versus buying a thought	Discusses the ineffectiveness of thought challenging. Cognitive defusion is explained using RFT principles. A wide range of defusion exercises are provided along with details of when to use defusion and how to develop one's own defusion techniques.
	Chapter 7: If I'm not my thought then who am I?	Introduces concepts of self as context and self as content. An exercise is used to show the arbitrary nature of self-conceptualisations. Self as content is linked to cognitive fusion to demonstrate its role in limiting behaviour. The chess board metaphor is provided to explain self as context. Exercises are used to demonstrate self as context and mindfulness.

Continued

Table 10

Continued

Week	Chapter title	Content of chapters and processes targeted
4	Chapter 8: Mindfulness	Introduces mindfulness, what it is not and how to practice it. A wide range of mindfulness exercises are provided to demonstrate the concept.
	Chapter 9: What willingness is and is not	Provides a more detailed account of acceptance and what it is not. An exercise helps readers identify what experiences they need to accept. A figure depicting a head full of painful experiences is used as a physical metaphor to represent acceptance.
5	Chapter 10: Willingness: learning how to jump	Works through first steps towards acceptance using exercises.
	Chapter 11: What are values?	Introduces values as chosen life directions and differentiates them from goals, feelings and outcomes using exercises and metaphor.
6	Chapter 12: Choosing your values	Uses exercises to help readers identify their values in different life areas and rate them in terms of importance and the degree to which they are living consistently with each value.
	Chapter 13: Committing to doing it	Introduces committed action and uses exercises to help readers to set goals, identify actions that they can take towards achieving their goals and consider expected barriers. Guidance on building patterns of effective action are provided with charts that can be used to track valued living over time.
	Conclusion: The choice to live is vital	Provides a summary of the material covered and reminds readers that valued living is a choice.

2.5 Intervention

Table 10 provides an overview of the recommended weekly reading from *Get Out of Your Mind and into Your Life* with a brief description of the topics and processes covered (Hayes & Smith, 2005). The book is 198 pages in total (excluding appendix and reference section), equating to an average of 33 pages (including figures and exercises) per week. Each chapter comprises information about the ACT model and includes examples, exercises and metaphors. Some exercises are experiential in nature (e.g. mindfulness or defusion techniques) while others involve writing or keeping a diary. The duration of the intervention and amount of weekly reading was discussed and agreed with the Clinical Psychologist within the service. In qualitative studies, dialysis patients have described their dialysis regimen as being characterised by

boredom and waiting (e.g. Moran, Scott & Darbyshire, 2009) with a typical haemodialysis patient requiring three four-hour sessions of dialysis each week. As such, participants would have at least 12 hours each week to undertake their reading. The protocol for a trial of computerised CBT self-help also proposes supplying self-help materials for patients to complete during in-centre haemodialysis (Hudson et al., 2016).

As described above, the guided aspect of the intervention comprised six weekly telephone calls lasting up to 30 minutes and conducted by WV. The content of the calls was structured around a series of questions which can be seen below.

1. Have you read chapters X and Y?
2. If so, how did you find it? If not, what got in the way?
3. Was there anything you would like to clarify with me (e.g. concepts, exercises)?
4. What did you like/not like about the chapter?
5. What did you find helpful/unhelpful in the chapter?
6. Did you do all the exercises? If so, how did you find them? If not, what got in the way?
7. Is there anything you would like to discuss in relation to chapter X?
8. Do you have any questions about the chapter?
9. Do you have any questions relating to your participation in the study?

After initial introductions and a check to ensure that the time was appropriate, participants were reminded that they would be asked a number of questions. They were advised that it would be helpful to have the manual in front of them during the call.

Common factor strategies (aspects of psychotherapy which are common across therapeutic modalities) such as active listening, warmth, empathy, summarising, reflections and questioning skills, were used to develop and maintain a therapeutic alliance with each participant. We did not assess the strength of the therapeutic alliance, however, as this was beyond the scope of the study.

There were several functions to the calls. Participants were asked whether they had read each of the prescribed chapters and completed all of the exercises therein. This allowed us to determine to what extent participants had adhered to the intervention, with follow-up questions examining barriers to adherence. Providing encouragement was another core function of the calls. When participants had not completed the chapters, they were given reassurance and encouraged to continue with the manual.

When participants had completed the chapters they were given praise to reinforce their efforts. Several questions gave participants the opportunity to discuss and clarify information. This served to support their understanding of the written material, exercises, therapeutic model and techniques, and provided time to troubleshoot any difficulties.

Although risk was not assessed explicitly during each call, in the event that a participant's responses or demeanour gave cause for concern, a risk assessment would be carried out. Ultimately, no risk issues arose during these calls. At the end of the call, participants were given the opportunity to ask any remaining questions relating to the intervention or trial procedure and a time for the next call was arranged. A reminder of which chapters to read over the subsequent week was also provided.

2.6 Framework analysis

As described above, framework analysis (Ritchie & Spencer, 1994) was used in the analysis of interview data. Like thematic analysis and qualitative content analysis, the framework approach allows the researcher to identify similarities, differences and relationships between different parts of the data before drawing descriptive or explanatory conclusions based on themes (Gale, Heath, Cameron, Rashid & Redwood, 2013). The output of the framework analysis, and a defining characteristic of the approach, is a matrix which allows the data to be analysed according to code or case (e.g. interviewee).

In selecting this method, there were two primary considerations: the research question and the epistemological position of the researchers. As a feasibility trial, we had pre-defined areas of interest relating to specific aspects of the trial procedure and intervention. Unlike thematic analysis, which focuses on themes emerging from the data, framework analysis emphasises *a priori* issues and as such allows the investigation of specific pre-defined themes. Furthermore, unlike some qualitative approaches, framework analysis is not tied to a particular epistemological or theoretical position and is therefore flexible to the approach of the researcher. This strengthens the rationale for its use here.

There is published guidance for conducting framework analysis in healthcare (Gale et al., 2013) and psychological research (Parkinson, Eatough, Holmes, Stapley &

Midgley, 2016). The analysis was carried out by WV based on this guidance. A brief, stage-by-stage account of our approach is provided below:

Stage 1: Transcription

Audio recordings were transcribed by a paid transcription service for time saving purposes. Given that the content is of primary interest in framework analysis, other conventions of dialogue, such as pauses, were not required.

Stage 2: Familiarisation

An initial read through of the transcripts allowed familiarisation with the data prior to coding. It is not necessary to review all of the data in framework analysis (Srivastava & Thomson, 2009), however, as there was relatively little data and as the transcription had been carried out externally, all of the data was reviewed.

Stage 3. Coding

Following familiarisation with the data, the transcripts were re-read and codes were applied to each line. These codes are essentially labels describing the content of the line. As an entirely deductive study, codes were pre-defined based on different aspects of the trial procedure and intervention (recruitment, randomisation, measures, support calls and self-help manual). There was an additional code labelled “treatment as usual” as the interview also investigated participants’ past experiences of treatment (i.e. whether they had previously accessed individual or group therapy, used psychopharmacological treatments or read self-help books). Data that did not fit into any of these codes were given the code “other”.

Stage 4. Charting data into a framework matrix

For each transcript, the data was summarised for each code, reducing the data while maintaining the original meaning of the content. Using a spreadsheet, the summarised data was charted into a matrix with each column heading representing an individual participant and each row heading representing a code.

Stage 5. Mapping and interpretation

For each code, similarities and differences between the data were identified providing a description of participants’ individual and collective perceptions of each aspect of the trial.

2.7 Individual level analysis

RCTs typically use between-group comparisons of measures of central-tendency using inferential statistical analyses. Such analyses were precluded by our small sample size, however, individual level analyses provide an account of how individual participants respond to interventions by comparing pre- and post-intervention outcomes. The Leeds Reliable Change Indicator software (Agostinis, Morley & Dowzer, 2008) can be used to examine whether individual changes in outcome scores are reliable and/or clinically significant.

Reliable change refers to instances when the change in an outcome score is sufficiently large that it is unlikely to be due to measurement unreliability (Jacobson, Follette & Revenstorf, 1984). To determine whether reliable change has occurred, the software calculates measurement variability, known as the reliable change index (RCI), by dividing the change in the individual client's score by the standard error of the difference for the outcome measure being used. If the RCI is greater than or equal to 1.96, then the change is statistically significant and there is a 95% certainty that reliable change has occurred. Such changes may represent both improvement in functioning and deterioration.

Clinically significant change refers to instances when the client's level of functioning following treatment improves to the extent that it falls outside the range of the dysfunctional population (Jacobson & Truax, 1991). Where a measure has an externally determined clinical cut-off score, this can be used to determine clinically significant change (e.g. on measures where high scores indicate poorer functioning, those falling below the designated cut-off have moved outside the range of the dysfunctional population). In the present trial, we used a cut-off of 10 for the PHQ-9 so clinically significant change refers to scores that fall under this cut-off, post-intervention. No clinical cut-offs are published for the EQ-5D-5L but an increase or decrease of 0.07 is considered a minimally important difference (Walters & Brazier, 2005). For the AAQ-II, no externally determined cut-offs are provided. In these instances, Jacobson et al. (1984) propose the use of one of three statistical criteria:

- a. If normative data for a non-clinical reference group (e.g. general population) is not available, to designate an outcome as clinically significant the post-intervention score should fall outside the range of functioning for the clinical population (e.g. 1.96 standard deviations).

- b. When normative data for a non-clinical reference group is available and scores from the non-clinical and clinical groups overlap, clinically significant change is indicated by the post-intervention score falling within the range of the non-clinical population (e.g. 1.96 standard deviations from the non-clinical population mean).
- c. When normative data for a non-clinical reference group is available and scores from the non-clinical and clinical groups do not overlap, clinically significant change is indicated by the post-intervention score falling closer to the non-clinical population mean than the clinical population mean.

In accordance with this guidance, criteria b was adopted to determine clinically significant change on the AAQ-II.

2.8 Ethical approval

The research protocol and supporting documents were submitted to the National Research Ethics Service Committee (NRES), North West, who granted ethical approval for the trial (see Appendix B for approval letter). To recruit from Nottingham University Hospital NHS Trust sites, ethical approval was sought and granted from the trust Research and Innovation department (see Appendix C for approval letter). Ethical approval was also granted from the University of Lincoln, School of Psychology Research Ethics Committee (SOPREC).

Our second recruitment procedure, which involved distributing screening questionnaires to all patients, was not part of our original protocol. As such, this required the submission of a substantial amendment to the NRES Committee and subsequent agreement from the local Research and Innovation department. Copies of approval letters can be seen in Appendix D and E.

2.8.1 Informed consent

Screening questionnaires were accompanied by a letter giving a brief overview of why we were requesting patients' information. Patients were advised that by completing the screening questionnaire they were consenting to their anonymised information being used in our research. This allowed us to collect data on rates of acceptance and psychological distress from individuals not enrolled in the trial.

Prospective participants were provided with a participant information sheet giving an overview of the study including: details of the purpose of the trial, who was eligible, how participants would be randomised, what was required of participants in each arm of the trial, what the potential benefits, risks and disadvantages were, how the research was funded and contact details for WV, NRES Committee, SOPREC and the local Patient Advice and Liaison Service (PALS). The information sheet also informed potential participants of their right to withdraw at any time during the trial and explained that all information would be treated as confidential. Prior to participation, participants were required to sign a consent form. Copies of the latest versions of the participant information sheet and consent form can be seen in Appendix F and G. To ensure that the participant information sheet and consent form were at an appropriate reading level, copies were given to two lay-persons who read through and confirmed readability.

2.8.2 Confidentiality

All participant information was treated as confidential and was not shared beyond those involved in conducting the research (see exception below). All electronic data was anonymised using corresponding identification numbers and stored on password protected computers. Hardcopy participant data was stored securely in the trial master file in a locked office at the University of Lincoln.

The limitations and one exception to confidentiality rules were given to patients in advance of any assessment data being collected. In the letter accompanying the screening questionnaire, patients were advised that if their responses indicated that they were experiencing significant psychological distress, then their family doctor would be notified by letter. This ensured effective risk management and gave individuals the opportunity to seek treatment from their family doctor, as appropriate. The intention to share this information with family doctors was repeated in the participant information sheet. Similarly, prospective participants were advised that if a member of the research team had concerns about the well-being of a participant or anybody else, then a breach of confidentiality would be warranted. Where possible, consent would be gained prior to sharing this information outside of the research team.

2.8.3 Iatrogenic effects

The term iatrogenic effect refers to the capacity for treatments to cause harm. It is estimated that three to six per cent of individuals who receive psychotherapeutic

treatment experience deterioration in their mental health (Mohr, 1995). No attempts have been made to estimate iatrogenic effects in self-help interventions. However, as with all treatments, such effects are possible.

ACT interventions encourage clients to abandon unhelpful avoidance behaviours and open themselves up to distressing private experiences such as thoughts, memories, emotions and physical sensations. In doing so, clients may experience some additional distress. However, there is considerable evidence that ACT interventions aimed at reducing experiential avoidance lead to positive benefits for clients (Hayes et al., 2006). The participant information sheet advised participants that discussing their problems could cause distress and that any concerns about their well-being would be shared with the Clinical Psychologist based within the renal service. This allowed participants to make an informed decision, bearing in mind the possible risks of participation.

3. Extended Results

This section provided further details on return rates for our screening questionnaire across units and the self-reported prevalence of various problems identified on the ET problem list. There is also an account of parametric assumption testing and the treatment of outliers. Finally, there is an examination of data pertaining to participants' past experiences of treatment, to provide an account of what patients receive as treatment as usual.

3.1 Screening procedure

Table 11 shows the number of screening questionnaires distributed and returned per unit. There was considerable variability in the return rate between units with a higher return rate at the satellite units when compared with the city units. The highest return rate was at satellite unit 2 where nearly half of the patients returned their questionnaires. The reason for this variability is unclear however it may relate to the way in which facilitating staff teams distributed and collected the questionnaires.

3.2 Problem list

Table 12 shows the frequency and percentage of screening questionnaire completers who reported each of the problems on the ET problem list. More than half of those who completed the screening questionnaire reported problems with pain, fatigue, sleep, getting around, and dry or itchy skin. The number of people who identified depression as a problem ($n = 31$) is consistent with the number meeting the cut-off for depression on the PHQ-9 ($n = 30$).

3.3 Outliers, normality testing and homogeneity of variance

A series of between group analyses were carried out to examine: a) differences between screening questionnaire completers and non-completers; and b) differences between participants in the ACT and treatment as usual conditions at baseline. The independent t-test is a commonly used method for evaluating the difference between two unpaired groups. It requires that the dependant variable is approximately normally distributed in both groups and that there are no significant outliers. Homogeneity of variance between the groups is also required. The identification and treatment of outliers for each variable in each group is described below. Where a variable was not approximately normally distributed, non-parametric Mann-Whitney U tests were computed.

Table 11

Percentage of questionnaires returned per unit

Unit	Questionnaires	
	Distributed	Returned
City unit 1, <i>n</i> (%)	100	32 (32)
City unit 2, <i>n</i> (%)	49	9 (18.4)
Satellite unit 1, <i>n</i> (%)	53	23 (43.4)
Satellite unit 2, <i>n</i> (%)	74	35 (47.3)
Total	276	99 (36.9)

Boxplots were used to check for outliers in age of completers and non-completers. This identified five outliers amongst completers and two amongst non-completers. Outliers were reduced to the next highest age that was not an outlier. Normality was assessed using visual inspection of normality plots and z-tests using a critical z-value of 3.29 as recommended for a sample of this size (Kim, 2013). Age was not normally distributed amongst those who completed the screening questionnaire with a skewness of -.91 ($SE = .24$) and kurtosis of -.11 ($SE = .48$). The absolute z-value for kurtosis was 3.76. A normal distribution in age was found amongst non-completers with a skewness of -.54 ($SE = .18$) and kurtosis of .001 ($SE = .36$). As age was not normally distributed for screening questionnaire completers, a Mann-Whitney U test was conducted.

Further checks for outliers, normality and homogeneity of variance were conducted prior to examining baseline differences between participants allocated to the ACT and control arms of the trial. Inspection of boxplots showed no outliers in age, years dialysing, PHQ-9, EQ-VAS and VLQ, however one outlier was identified for the EQ-5D-5L index value and another for the AAQ-II. These outliers were reduced to the next lowest values that were not outliers.

Normal distributions were found in both groups for age, PHQ-9, EQ-5D-5L index score, AAQ-II and VLQ, as assessed by Shapiro-Wilk's test ($p = >0.05$). Shapiro-Wilk's is regarded as an appropriate method for assessing normality in samples less than 50. A non-normal distribution was found in years dialysing for the ACT condition ($p = .04$) and EQ-VAS in the control condition. As the normality assumption was violated, Mann-Whitney U tests were administered to examine between-group differences in years dialysing and EQ-VAS. Homogeneity of variance, as assessed by Levene's test, was found for age ($p = .94$), PHQ-9 ($p = .54$), EQ-5D-5L index value ($p = .37$), AAQ-II ($p =$

Table 12

Proportion of each problem on the problem list reported by screening questionnaire completers

Problem	<i>n</i> (%)
Getting around	56 (58.3)
Pain	55 (57.3)
Fatigue	54 (56.8)
Skin dry/itchy	51 (53.1)
Sleep	50 (52.1)
Tingling in hands/feet	44 (45.8)
Breathing	36 (37.5)
Worry	35 (36.8)
Bathing/dressing	33 (34.4)
Sadness	32 (33.7)
Depression	31 (33)
Feeling swollen	31 (32.3)
Eating	27 (28.1)
Nervousness	27 (28.4)
Nausea	25 (26)
Changes in urination	24 (25)
Constipation	23 (24)
Indigestion	22 (22.9)
Nose dry/congested	22 (22.9)
Fears	21 (22.1)
Transportation	21 (22.1)
Diarrhoea	19 (19.8)
Dealing with partner	17 (17.9)
Sexual	11 (11.5)
Dealing with children	10 (10.5)
Housing	9 (9.5)
Fevers	7 (7.3)
Mouth sores	6 (6.3)
Relating to God	5 (5.3)
Work/school	4 (4.2)
Loss of faith	3 (3.2)
Child care	1 (1)
Insurance	0 (0)

.74) and VLQ ($p = .46$). As each of these variables met all relevant assumptions, independent t-tests were conducted.

To examine whether psychological inflexibility, as measured by the AAQ-II, was correlated with psychological distress, two Pearson's product-moment correlations were computed. The first examined the relationship between psychological inflexibility and depression, as measured by the PHQ-9. Visual inspection of a scatter plot revealed one outlier which was removed prior to the analysis. The second analysis

examined the relationship between psychological inflexibility and general anxiety, as measured by the GAD-7. A scatter plot was inspected prior to analysis but in this instance no outliers were identified.

3.4 Treatment as usual

As a feasibility trial using a treatment as usual control arm, it was important to determine what treatment as usual typically looks like. Interviewees were asked about their experiences of previous treatments including psychopharmacological treatment, individual or group psychotherapy and self-help. Of the six participants interviewed, four had not been prescribed anti-depressant medication since being diagnosed with CKD. Two participants had been prescribed Citalopram although only one of these participants had a current prescription. Two participants had never received any psychological therapy since being diagnosed with CKD while three had received various interventions. Two participants had seen the Clinical Psychologist at the renal unit, another participant had received four sessions of CBT but did not complete a full course of treatment. Another participant had seen a Psychiatrist when she was first diagnosed. Five out of the six participants had never been to a therapeutic or meditative group while one had attended one session of art therapy. Only one participant had previously read a self-help book although she could not recall the title.

4. Extended Discussion

This section will expand upon issues discussed in the journal paper regarding matters of recruitment, adherence and other aspects of feasibility. A consideration of the strengths and limitations of the study are provided as well as recommendations for future research directions.

4.1 Feasibility: Recruitment

Recruitment difficulties are not uncommon in health research. One systematic review found recruitment problems in 63% of the 114 RCTs included (McDonald et al., 2006). Recruitment problems are well documented in depression trials specifically, with numerous studies failing to reach their target recruitment numbers (e.g. Woodford, Farrand, Bessant & Williams, 2011) or failing to recruit altogether (Hunt, Shepherd & Andrews, 2001; Ruddell, Spencer, Hill & House, 2007).

Recruitment problems have been reported in other trials of telephone-supported self-help with one trial reporting only 1% of individuals with mild to moderate depression who were sent study information packs, consenting to the trial (Woodford et al., 2011). The intervention in this case was a computerised CBT course with minimal telephone support and the recruitment methods and target population were also dissimilar to those of the present trial. Despite the dissimilarities, this highlights that difficulties recruiting into self-help studies is not unique to our trial.

While it has been argued that recruitment experience is unique to each trial (Baquet, Henderson, Commiske & Morrow, 2008), some studies have attempted to identify recruitment barriers that might be common across mental health research. A meta-synthesis examining factors affecting recruitment into depression trials identified three emergent themes: the participant's health state, their attitude toward research and trial interventions; and the communication and relationship between participants, gatekeepers (e.g. carers and clinicians) and the research team (Hughes-Morley, Young, Waheed, Small & Bower, 2014). These emergent themes provide a framework for considering possible reasons for our recruitment failure.

4.1.1 Health state

In their review, Hughes-Morley et al. (2014) found that certain presenting characteristics of depression (e.g. lack of confidence) could have a negative impact on

recruitment. They also found that the existence of co-morbid problems had a confounding effect. The impact of these aspects of health state on our recruitment is discussed in the journal paper above.

The authors of the review also found that participation was affected by perceptions of the impact of participation on their health state which involved a cost-benefit analysis. Clearly this is speculative, but it is possible that patients who we approached about participation did not perceive there to be a benefit. This is especially likely if they did not believe they were depressed (as discussed in the journal paper) or had a poor understanding of the potential benefits of supported self-help. Perhaps more information about self-help during recruitment would have addressed this. This could have been achieved by inviting individuals to information sessions or by providing more detail in the participant information sheet. However, it seems unlikely, given their reluctance to enrol in the trial, that many individuals would attend an invited information session, if it had been available.

As well as failing to perceive benefits, eligible patients may have perceived there to be a considerable cost to participation, primarily in terms of the time commitment involved. This is in light of the extensive treatment burden already experienced by haemodialysis patients.

4.1.2 Attitude toward research

The second factor identified by Hughes-Morley et al. (2014) relates to potential participants' attitudes toward research and trial interventions. They report that individuals are more motivated to participate in depression trials if doing so allows them to access an otherwise unavailable treatment. Telephone-supported self-help is not available as a standardised treatment at our recruitment sites but psychological support is available through the renal clinical psychologist. Eligible patients who declined participation also declined psychological support outside of the trial indicating that, even if they had perceived this to be a treatment that was otherwise unavailable, this would not have been a motivating factor.

The reviewers found that participants were more likely to decline participation if they had a previously negative experience of the intervention. Although self-help materials are widely available, our framework analysis indicated that only one of the six participants interviewed in our trial had previously used a self-help book. While it is

difficult to generalise from such a small sample, it suggests that past negative experiences of self-help are an unlikely cause for our low recruitment numbers as few eligible patients are likely to have utilised self-help previously.

4.1.3 Engaging the patient

The third major theme identified by Hughes-Morley et al. (2014) was the relationship between researchers, participants and gatekeepers. Of particular relevance to the present trial is the issue of stigma. The reviewers found that depression was viewed as a highly stigmatised mental health problem. Furthermore, participants did not view their own difficulties to be of the same clinical severity as depression.

When approaching participants in the present trial, we were careful to avoid the potentially stigmatising diagnostic label “depression”. Potential participants were advised that the screening questionnaire indicated that they might be feeling down or low in mood. It was anticipated that the use of the word “depression” during the initial conversation about the research could discourage further discussion and subsequent participation. However, estimated prevalence rates for depression in ESRD were detailed in the participant information sheet. It was hoped that by demonstrating how common depression is within the dialysis population, it might reduce stigma and encourage altruistic motivations for participation (i.e. individuals might be willing to participate knowing that a large number of dialysis patients may be helped through the development of a new treatment for depression). It is possible that our use of the word “depression” discouraged patients from participating due to the associated stigma or because they did not recognise themselves as depressed.

Future depression trials in ESRD might benefit from avoiding diagnostic labels altogether. For example, our study could have been sold as an intervention to improve well-being rather than as a treatment for depression. In doing so, patients would not be deterred by the double stigmatisation of being perceived as depressed and being treated for depression.

4.1.4 Experiential avoidance

The factors identified by Hughes-Morley et al. (2014) may offer a partial account for our recruitment difficulties however, the avoidance paradigm, central to the ACT model, provides further insight. The rationale for an ACT intervention in ESRD was partly based on research highlighting the clinical significance of experiential avoidance and

acceptance in the psychological well-being of ESRD patients (Gillanders, Wild, Deighan & Gillanders, 2008; Ibrahim, Chiew-thong, Desa, Razali, 2013; Keskin & Engin, 2011; Poppe et al., 2013). Indeed, although we acknowledge the limitations of the AAQ-II, our findings indicated strong correlations between psychological distress (self-reported symptoms of depression and anxiety) and psychological inflexibility/flexibility. If distressed haemodialysis patients are more likely to engage in experiential avoidance as a coping strategy, then these avoidant behaviours may also act as a barrier to accepting treatment.

Several aspects of psychological treatment might elicit avoidance behaviour. Psychological treatment involves an open exploration of emotional experiences. This can be challenging and aversive, and may lead some individuals to avoid treatment. Indeed, studies have shown that undergraduate students who have a tendency to avoid emotions are less likely to seek treatment, although the use of non-clinical samples mean that these findings lack generalisability (Ciarrochi & Deane, 2001; Komiya, Good, & Sherrod, 2000). Similarly, students' expectations about the extent of emotional expression in treatment have been shown to predict both treatment-seeking attitudes and treatment-seeking behaviour (Vogel, Wester, Wei & Boysen, 2005). Emotional suppression, a form of avoidance, is related to greater levels of depression in haemodialysis patients (Gillanders et al., 2008). This highlights a propensity amongst depressed dialysis patients to avoid emotion and may explain why some individuals did not want to participate in our trial.

Another aspect of psychological treatment that might elicit treatment avoidance is self-disclosure, the process by which clients divulge private feelings, thoughts and beliefs (Leaper, Carson, Baker, Holiday & Myers, 1995). There is variability in the extent to which people feel comfortable sharing personal and emotionally charged information with others and this has been shown to be a unique predictor of treatment-seeking behaviour (Vogel & Wester, 2003; Vogel et al., 2005). In a cross-sectional study, individuals who were uncomfortable discussing personal issues were 5-times less likely to seek treatment than individuals who were comfortable (Diala, Muntaner, Walrath, Nickerson, LaVeist & Leaf, 2001). It is possible that avoidance of self-disclosure deterred enrolment in the present trial. Other factors that have been implicated in treatment avoidance are social stigma (Komiya et al., 2000) and anticipated utility and risks (Vogel & Wester, 2003), both of which were identified in the Hughes-Morley et al. (2014) review as barriers to treatment. Again, these may be important considerations with regards to the current research.

4.1.5 Treatment rates

Depression treatment rates are low in the ESRD population and although this is partly due to under-diagnosis (Hedayati, Bosworth, Kuchibatla, Kimmel & Szczech, 2006), other explanations have been proposed. In a study of peritoneal dialysis patients, 55% of those identified as having depression refused further assessment and treatment, even when they were informed of the possible advantages (Wuerth, Finkelstein & Finkelstein, 2005). The main reasons for treatment refusal were denial that they were depressed, unwillingness to take additional medication, refusal to meet with the practitioner and the perception that depression was a sign of weakness and a potential source of stigmatisation. In another study, only 17% of haemodialysis patients identified as being depressed initiated treatment for depression, even after healthcare providers were informed of the diagnosis (Weisbord et al., 2013). The authors did not determine whether this was due to a lack of intention to treat on the part of the medical team, or because patients declined treatment. Furthermore, it is unclear what treatments were available to patients.

These findings illustrate that the ESRD population might be especially reluctant to engage in treatment for depression and therefore, may be reluctant to participate in a trial where they might receive such a treatment. This hypothesis is supported by the finding that individuals who declined participation in our trial also declined psychological support outside of it. Having said that, other trials of non-self-help psychological interventions have successfully recruited ESRD patients (e.g. Cukor et al., 2014) indicating that there must be something particular about our recruitment methods or intervention that discouraged participation.

4.1.6 A failed trial?

In light of our recruitment troubles, one might be tempted to describe this as a failed trial. However, this does not take into account our aims. We set out to establish the feasibility of an RCT examining ACT telephone-supported self-help for depression in ESRD, and to that end, the trial addressed our aims – there is clear evidence that a full-scale trial adopting the present procedure is not feasible. However, ACT has shown effectiveness in other long-term conditions and we were able to demonstrate a relationship between the central ACT process – psychological flexibility – and distress in our sample. It is important, therefore, to consider how best to approach ACT interventions in ESRD while avoiding the recruitment difficulties encountered here.

A central consideration is how an ACT self-help intervention is promoted to ESRD patients. Evidently, our intervention was not appealing when offered as a treatment for low mood or depression, and as discussed, this may have been a factor in our low recruitment numbers. However, as briefly mentioned above, ESRD patients may have found the intervention more attractive had it been presented in a different way. For example, it could be promoted as an approach which helps individuals to do more of what is most important to them (i.e. valued living), or as way of improving quality of life. It is important to note that we have no data to suggest that this would address recruitment (or adherence) difficulties, however, such an approach would be more consistent with the ACT model. The ACT approach makes no hypotheses regarding distress reduction, in fact the whole model centres on accepting emotional pain in the service of values. This is perhaps captured most succinctly by the idea of “growing the person” rather than “shrinking the problem”. As such, the intervention would not be a treatment for depression but a way of reducing dysfunctional avoidant behaviour and encouraging ESRD patients to engage in valued action.

Whether or not this would go some way to resolving recruitment difficulties is conjecture. However, without distress reduction as a primary outcome, inclusion criteria could be broadened, providing a larger pool of eligible patients from which to recruit. This approach has been used in other self-help trials. For example, a study comparing two self-help interventions for chronic pain, one based on applied relaxation and the other on ACT, successfully recruited 90 individuals from a chronic pain clinic in Sweden (Thorsell et al., 2011). Despite having depression and anxiety as outcomes, no distress cut-off was used and only two inclusion criteria were stipulated; participants had to be accessible during the 7-week intervention period and have sufficient literacy skills. Although there are obvious differences when compared to the present trial (e.g. population and setting), this study demonstrates the effectiveness of using broader inclusion criteria. Unfortunately, the authors do not state how the intervention was promoted to potential participants.

In terms of applying this to the present study, one option would be to invite participation from all haemodialysis patients receiving treatment at the recruitment sites, regardless of their self-reported level of distress. Some eligibility criteria would still be applied, for example, participants would still need to be aged 18 years or over, be dialysing for six months or longer, have adequate English language speaking and reading ability, and an absence of sensory impairments likely to impede engagement in treatment. However, no distress cut-off would be applied.

Another option would be to use of a lower cut-off on the PHQ-9. Again, this would likely produce a larger pool of eligible participants with the possibility that this might increase overall recruitment numbers. This is however speculative and more research is needed to examine whether individuals with milder symptoms of depression are more motivated to participate in supported self-help interventions. The advantage to using a lower cut-off is that it is consistent with a stepped-care model of treatment in which individuals assessed as experiencing more severe levels of distress receive a more intensive intervention (e.g. face-to-face therapy). As such, although it is unclear whether this would resolve recruitment difficulties, it would be consistent with NICE guidance for the treatment of depression in long-term physical conditions (NICE, 2009). Further discussion of the use of a lower PHQ-9 cut-off is provided under the next subsection heading.

While recruitment difficulties are common in health research, the review by Matcham et al. (2014), examining self-help interventions for psychological distress in patients with physical illness, shows that many self-help trials have successfully recruited individuals with long-term conditions. They identified 29 trials eligible for inclusion in their systematic review, all of which recruited more than our target sample size. Some of these studies are not appropriate for comparison with the present study due to significant differences in setting, population and intervention, however, examination of comparable studies may offer insights into how recruitment in the present trial could be improved. For example, in a Dutch trial of CBT-based self-help for people with rheumatic disease, Garnefski et al. (2013) recruited 82 individuals through patient organisation websites. Interested individuals were referred to a website where they could access study information and determine their eligibility. There are several kidney patient organisations in the UK, the foremost being the British Kidney Patient Association. Use of patient association websites would have broadened our recruitment pool to include anyone accessing these websites across the UK, rather than being limited to individuals receiving treatment at our recruitment sites. Bearing in mind our difficulties, future trials of self-help in ESRD may benefit from combining in-centre and online recruitment strategies.

An alternative way of widening the pool of potential participants is through a multi-centre recruitment strategy. In a UK trial evaluating an evidence-based self-help guidebook to improve knowledge, anxiety and quality of life in people with ulcerative colitis, 240 participants were recruited across six hospital sites (Kennedy, Robinson, Hann, Thompson & Wilkin, 2003). There are advantages and disadvantages to this

approach. In terms of advantages, multi-centre recruitment provides a more representative sample and may allow the target sample size to be reached more quickly. However, recruiting from multiple organisations in different geographic regions is a time and resource heavy venture and may be beyond the scope of a feasibility trial. Once feasibility has been established, multi-centre recruitment may be the optimal strategy.

4.2 Feasibility: Assessment

Interview data indicates that our assessment methods were acceptable and appropriate. Completion rates and the extent of missing data are further indicators of acceptability. We gained a 36.9% return rate at screening, comparable to the return rate in the recent NHS GP Patient Survey, which recorded a national response rate of 35.7% (Ipsos Mori, 2016). However, our questionnaires were distributed by staff teams at dialysis units while the GP Patient Survey was postal. A more fitting comparison is with the National Kidney Care Audit Patient Transport Survey which recorded a 67% return rate, with questionnaires distributed at renal units (NHS Information Centre, 2011). In comparison to this, our return rate appears low, however, the Patient Transport Survey addressed a highly pertinent and almost daily issue for patients – how they get to-and-from their treatment – and revealed a rather negative picture for patients reliant on hospital transport. It is plausible that patients would be more motivated to respond to a questionnaire when it relates to a highly salient issue over which they have high levels of dissatisfaction. However, our response rate is also low compared to other hospital-based surveys including the English Cancer Patient Experience survey (67%; Macmillan Cancer Research, 2013) and the UK Adult Inpatient Survey (49%; Department of Health, 2010).

Our questionnaire was five pages in length and while it is always problematic separating the effect of questionnaire content from length, longer questionnaires are typically associated with lower response rates (Rolstad, Adler & Ryden, 2011). Yammarino, Skinner and Childers (1991) found significantly lower response rates for questionnaires longer than 4 pages although this was not replicated in another study (Iglesias & Torgerson 2000). Furthermore, both of these studies, as with much of the research in this area, are based on postal survey data. Response rates might have been boosted if we had reduced the screening questionnaire to the PHQ-9 alone, however this would not have allowed us to collect data on psychological flexibility and

would have denied us the opportunity to examine which distress measures are most acceptable.

Despite our response rates, missing data was minimal. For participants enrolled in the trial there was no missing data at all and at screening, there were no missing data points for the PHQ-9 and GAD-7. These measures are used widely across the NHS and both are recommended in NICE guidelines (NICE, 2011). The present findings confirm the acceptability of these measures in this population. There were a small number of missing data points on the AAQ-II with more on the problem list and more still on the ET. The latter two questionnaires were placed towards the end of the battery and patients may have lost interest at this point or not realised that there were additional pages. Although it is not entirely clear why the ET in particular had more missing data points, it suggests that the PHQ-9 and GAD-7 may be more acceptable as distress screening tools in renal services. When taken alongside interview data, the shortage of missing data indicates that overall our assessment methods were acceptable. Reducing the questionnaire length might serve to increase response rates.

Although largely acceptable to participants, our assessment methods failed to effectively identify those for whom self-help might be most suitable. In a stepped-care model, the level of intervention is determined by the level of need, with low-intensity interventions aimed at individuals in the mild to moderate range of symptom severity. The iDiD trial of telephone-supported computerised CBT for distress in haemodialysis patients, currently underway in London, proposes the use of baseline PHQ-9 and GAD-7 scores to identify those individuals for whom their intervention is most appropriate (see Hudson et al., 2016 for protocol). Individuals who fall within the mild to moderate range on these measures (5-19 on PHQ-9 and 5-14 on GAD-7) are deemed eligible for the trial, while those who fall into the sub-clinical or more severe range are not. In the present trial, PHQ-9 scores at screening ranged from 0 to 27 with an eligibility cut-off of ≥ 10 .

Had we used the cut-offs proposed in the iDiD protocol, 31 patients deemed ineligible by our cut-off, would have been eligible. Conversely, nine patients who were eligible by our cut-off would have been ineligible for being above the mild to moderate range by the iDiD criteria. This would have provided a net gain of 22 patients to approach. Interestingly, only one of the nine patients who would have been excluded by the iDiD criteria consented to participate in the present trial. Furthermore, this individual was the only person to formally withdraw from the trial. By adopting the iDiD criteria, we would

have broadened the pool of eligible participants, including those with milder depressive symptoms for whom self-help might have been more acceptable and more appropriate. In addition, those who fell into the severe range (PHQ-9 score >19), who were evidently most reluctant to participate in the trial, would have been excluded.

In light of this, it could be argued that our cut-off was too high, excluding individuals who may have been best placed to benefit from self-help. However, we had a strong justification for using this higher cut-off. As discussed previously, there is considerable symptom overlap between depression and ESRD. Several of the items of the PHQ-9 – those addressing the cognitive and somatic symptoms of depression – relate to symptoms commonly reported by ESRD patients, namely trouble sleeping, lack of energy, changes in appetite and trouble concentrating. Individuals with ESRD may score highly on these items without meeting diagnostic criteria for depression. As such, a cut-off of 5 may lack the specificity to correctly identify depression in ESRD patients.

The Hudson et al. (2016) protocol proposes cut-offs based on a sample of the general population recruited through primary care clinics (Kroenke et al., 2001) while our cut-off was based on a sample of haemodialysis patients, reporting a 92% specificity and sensitivity when using the ≥ 10 cut-off (Watnick, Wang, Demadura, & Ganzini, 2005). Using a lower cut-off may have given a larger pool of participants but it is questionable whether all of these individuals would meet diagnostic criteria for a depressive disorder. As a feasibility trial, our aim was to determine the parameters of a hypothetical full-scale trial. If our inclusion criteria fail to identify individuals experiencing the target clinical problem, then a full-scale trial would be unable to evaluate the effectiveness of our intervention for this problem. While it is worth considering a more liberal cut-off, our higher cut-off remains defensible, particularly as it provided a prevalence rate for depression that was in the range of estimates identified in previous studies (e.g. Wang & Watnick, 2004). Using a cut-off of >5, the prevalence of depression in our screened patients would far exceed these estimates.

4.3 Feasibility: Self-Help

According to Good Practice Guidance on the Use of Self-help materials within IAPT Services, an important consideration when designing self-help interventions is the readability and cultural appropriateness of the materials (IAPT, 2010). One participant in the present study found some of the language in the self-help manual too complex and also thought that the material was more relevant to a North American audience.

Although this is only one person's perspective, it is worth considering how the content of the self-help book may have effected adherence. It seems likely that participants may be deterred from reading a book if it is beyond their level of literacy and if the content seems irrelevant to them.

The self-help manual is a general self-help book based on ACT principles. It is not specifically written for haemodialysis patients. The trans-theoretical nature of the ACT model means that this is less problematic for ACT than it might be for other therapeutic approaches (e.g. CBT), but participants might have engaged better if the materials seemed more applicable to the haemodialysis patient experience. There is however, no data to support this assertion. The original intention had been to design an ACT self-help manual specifically aimed at haemodialysis patients but this seemed overly ambitious in the time-frame available. In hindsight, although this may have improved adherence, it is unlikely to have impacted recruitment.

The MRC argue that recruitment and retention are better in trials where potential participants value the intervention on offer (Craig et al., 2008). Our interview data on participants' experiences of past psychotherapeutic treatments indicated that only one had used a self-help manual. Again, this lacks generalisability due to the small sample size but one might hypothesise, given that the proliferation of self-help is relatively recent and that the average age of these patients indicates an older group, that the ESRD population have little understanding of self-help and the concept of self as a mechanism of change. In their review, Khan et al. (2007) found that peoples' understanding of self-help relied on past experiences. It is reasonable to assume that individuals who have no past experience of self-help will have a poor understanding of it and are unlikely to value it as a prospective intervention. Furthermore, patients in a medical setting may be more likely to view their role as a recipient of treatment rather than an active agent in it. This lack of understanding could account for our low recruitment, although this seems less likely given that patients did not want psychological support, regardless of how it would be delivered.

4.4 Strengths

In addition to our strong mixed methods design, which allowed a triangulation of qualitative and quantitative data in order to answer our research aims, there are some other notable strengths. Firstly, WV was unaware of the computer-generated random number sequence used in the randomisation procedure, reducing the risk of allocation

bias. Further risk of bias was removed by allocating people on a participant-by-participant basis.

The control of concomitant treatments is important in RCTs as this allows any improvement in outcomes to be attributed to the intervention under investigation rather than other treatments. Concomitant treatments were controlled to the extent that individuals were excluded if they were receiving psychological treatment at the time of recruitment. Participants were also advised to inform the research team if they started treatment.

As a feasibility trial, it is a strength that we were able to evaluate the effectiveness of two recruitment strategies, even if this was only due to the ineffectiveness of our initial strategy. A strength of our second recruitment strategy is that we actively approached everyone who met the PHQ-9 cut-off for depression unless they were already receiving psychological treatment within the service. Previous trials of self-help have utilised recruitment strategies that require potential participants to actively respond to a study information pack (e.g. Woodford et al., 2011). Certain depression specific symptoms, such as low motivation, might prevent some participants from responding to invitations of this kind, particularly as depressed individuals frequently have low expectations for treatment outcomes (Prins, Verhaak, van der Meer, Penninx & Bensing, 2009). By actively approaching all patients who met the PHQ-9 cut-off we eliminated this problem.

4.5 Limitations

There are several limitations to our methodology, however the impact of many of these limitations is neutralised by the fact that the trial proved unfeasible. As previously discussed, low recruitment numbers and poor adherence prevented more in-depth analysis into which aspects of the ACT model and delivery format might be most helpful for ESRD patients. Indeed, only two participants in the ACT group were interviewed and only one of those had read the whole book. This meant very little was learnt about the content of the book and in terms of which bits were helpful, acceptable and relevant. However, even if we had reached our target recruitment and adherence had been high, the design precluded further analysis regarding the active ingredients of the intervention.

As discussed earlier, some research suggests that self-help is only beneficial when therapeutic guidance, such as weekly telephone calls, is provided. It is argued that guidance gives added value due to the effects of the therapeutic relationship (Glasman, Finlay & Brock, 2004), something that is absent in an unsupported self-help intervention. In order to determine whether this was the active ingredient in our intervention, an assessment of the therapeutic alliance would be needed with analysis focusing on the relationship between alliance and outcomes. Our use of the AAQ-II as a process measure instils additional problems in terms of identifying the active ingredients. The limitations of the AAQ-II are discussed in more depth above. RCTs are useful for identifying which treatments are helpful for which people, but in developing new interventions it is important to understand which aspects of the intervention make it work. To this end, single-case experimental designs and component studies, in which researchers try to isolate the effects of different ingredients by comparing treatments with and without them (Ahn & Wampold, 2001), are better suited. For our purposes (i.e. determining the feasibility of an evaluative trial), a two-armed RCT design was appropriate. Moreover, given our difficulties recruiting enough participants for two arms, recruiting enough for a third arm, where participants just receive the self-help book without telephone support, seems fanciful.

The factors that might account for our recruitment difficulties have been discussed in great detail however much of this speculative. Our design did not allow us to gather more detailed information about why people declined participation but it is true that we failed to recruit our target sample size. Low recruitment numbers are only a limitation to the extent that it precluded further investigation of the ACT model and delivery format. It did not prevent us from achieving our primary aim of determining the feasibility of a full trial.

An arguable weakness of our design is the use of a treatment as usual control group. Öst (2008) argues that the best RCTs compare the active treatment under evaluation with another empirically documented active treatment. However, our small sample size precluded any between group analysis and was focused more on issues of feasibility rather than effectiveness. For these reasons it was not essential to use an active comparison group and it seems unlikely that this would have made the trial any more appealing to patients.

Under ideal circumstances, frequent recordings of therapy sessions should be checked for therapist competence and adherence to the therapeutic model. In the present trial,

these checks were not made. Again this did not prove to be overly problematic as participants' poor adherence to the manual meant that they had rarely completed the necessary chapters in order to discuss the content.

A final limitation relates to the information given to participants during recruitment. Two participants expressed that the randomisation procedure might be unfair, depriving patients of the psychological support that they might need. This suggests that a proportion of participants, and perhaps potential participants, did not understand the rationale for randomisation or the ethical basis of clinical equipoise. There is a particularly strong argument for clinical equipoise in this instance as neither ACT nor self-help interventions have been evaluated with this population. Although it is clearly stated within the participant information sheet that our intervention had not previously been evaluated, it is not discussed in relation to the randomisation procedure. More work was needed to communicate this information more effectively. An amendment to the participant information sheet would be the best way to achieve this but as this is highlighted as a specific issue, it might be helpful if the purpose of randomisation and the ethical justification for it, is explained verbally when individuals are approached for recruitment.

In spite of this, all interviewed participants stated that the information provided was clear and we have no data to suggest that a misunderstanding of randomisation and clinical equipoise discouraged individuals from enrolling in the trial. All those who met the cut-off for depression and declined participation were asked if they would like any other support separate to the trial (e.g. referral to psychology). Given that no-one accepted this invitation, it suggests that participation was not rejected on the grounds that depressed patients were concerned that they would be randomised to the control group and therefore not receive psychological treatment.

4.6 Research implications

We have shown that psychological flexibility is related to psychological distress in haemodialysis patients, although this relationship may be overstated given the weaknesses of the AAQ-II. However, this finding is consistent with previous studies highlighting avoidant coping behaviours as possible factors associated with distress in ESRD (e.g. Gillanders et al., 2008). Further research examining the significance of ACT processes in ESRD is warranted, as are trials to determine the most effective and acceptable formats for delivering ACT interventions.

As well as the specific considerations for future research already mentioned in this discussion, one possible avenue for prospective studies might lie in chronic pain. More than half of the participants in the trial reported that they were troubled by pain, a figure consistent with previous research on ESRD pain burden (Davison, 2003; Fainsinger, Davison & Brenneis, 2003). Chronic pain remains an inadequately managed, under researched and undertreated problem in ESRD and one that impacts almost every aspect of health-related quality of life (Davison, 2007). There is now a considerable evidence-base for ACT for chronic pain (Hayes et al., 2006) and it has shown comparable outcomes to the more established CBT model (Veehof, Oskam, Schreurs & Bohlmeijer, 2011).

In light of the high prevalence and inadequate management of chronic pain in ESRD, as well as the burgeoning evidence-base for ACT, future research examining the acceptability and efficacy of ACT for chronic pain in ESRD is warranted. Careful consideration to determine the most appropriate and acceptable formats for delivering these interventions is needed. It seems likely that pain, and psychological treatments for pain, would not be as stigmatised as depression, particularly in the highly medicalised environment of the renal unit. As such, a trial of ACT for pain might not experience the same recruitment problems faced by our trial.

5. Reflective Section

This section provides a critical account of my experiences of the research process. My perception of the research and its potential merits have changed considerably during the course of the research. It is interesting to contrast my perceptions of the research at three key points; 1. during the development of the study design; 2. during recruitment and data collection; and 3. during the analysis and write-up. At this first time point, when the study was in its infancy, I had high expectations about what I could achieve. Data on the pervasiveness of depression in ESRD highlighted a highly prevalent problem with significant implications for health-related outcomes. Furthermore, there was little research on the efficacy of psychological interventions for this population and no studies looking at ACT or self-help. I had met with and discussed the research with my field supervisor, a Clinical Psychologist working in a renal service, and she recognised depression as an unmet need. Indeed, most renal services in the UK have access to Clinical Psychology and yet there appeared to be very little evidence-base for psychological interventions in this area. It seemed like a perfect project with significant clinical and research implications. The number of people with ESRD was steadily increasing and depression was a highly prevalent problem with virtually no psychotherapeutic evidence-base. There was scope to contribute in a meaningful way to the evidence-base and perhaps trigger further research on the ACT model in ESRD.

Consideration of the practicalities also seemed promising. I had an enthusiastic field supervisor with excellent local knowledge of the patient group and their psychological needs. There was a pool of several hundred patients across four dialysis units and if prevalence estimates were as high as some research indicated, recruiting the designated sample size would not be difficult. As a feasibility trial, I knew that I only needed a small sample and that the trial did not need to be fully powered. The design was relatively straight forward and would give me experience of both qualitative and quantitative methods.

Fast forward to the recruitment phase and things appeared very different. I was investing a vast amount of time trying to recruit participants and was struggling to muster much enthusiasm for participation from patients. The initial recruitment procedure involved a member of unit staff approaching patients and inviting them to speak with me about the research. Most were obliging but almost universally they denied that they felt low in mood. It was challenging to convince individuals who did not

perceive there to be a problem that a self-help manual and phone conversations would be of benefit to them. Although it meant considerable delay, it was agreed that an alternative recruitment strategy might be the answer and this required a substantial ethical amendment. We hypothesised that by screening all patients, we could identify those most in need of our intervention and approach them armed with objective data, in the form of the completed PHQ-9, demonstrating that they might be struggling with their mood. Although ultimately this proved more successful than our initial recruitment procedure, I still struggled, recruiting less than a third of the desired sample size.

Not only did many renal patients not want to participate in the trial, they also rejected any psychological support outside of the trial. There was a disparity here between my perception of clinical need and reality. I had assumed, given the high prevalence of depression and limited availability of psychology within the renal service, that there was a significant unmet need. Many patients experienced depression and I presumed that they would want help to tackle this. Although I could see that self-help might lack appeal, the fact that patients did not want psychological support separate to the trial suggested that their lack of enthusiasm for the trial was not entirely due to the intervention on offer. My perception of the trial at this time was profoundly negative as it seemed that I was wasting my time on a failed trial.

It was at this time that I started to question my approach to the research. As a scientist-practitioner, I considered how I would approach this as a clinician rather than a scientist. ACT does not try to target a reduction in psychological distress and makes no hypotheses about this. Perhaps ESRD patients would benefit from an ACT intervention as a way of improving quality of life or increasing valued action, rather than reducing distress. If this had been my approach, inclusion criteria could be much broader as specific cut-offs would not need to be met. When seeing patients in clinic, I do not expect them to meet a certain cut-off on a distress measure before I agree to help them (although this may be true in some stringent services). Indeed, as a clinician, I tend to discourage therapy goals around distress reduction and try to focus more on behavioural change. In research terms, by ignoring cut-offs it might be difficult to demonstrate improvement because scores may already be quite high at baseline (where high = better functioning). However, by broadening inclusion criteria, it might have allowed us to recruit the target sample size. In doing so, we may have had more proof of principle and acceptability data allowing us to draw stronger conclusions about the utility of the model and delivery format.

Looking back now, I am surprised that I became so tied to depression as a clinical problem and depression measures as a way of identifying those most in need of psychological help. I have always been critical of diagnostic systems and the biomedical model of mental health, avoiding pathologising language in my clinical practice and focussing on functional change. Since first being exposed to ACT as an Assistant Psychologist, I have been drawn to the ACT principle of destructive normality and admired the ACT model for its trans-diagnostic approach. I am attracted to positive psychology (Seligman, 2002) and other strengths-based approaches and like the ACT concept of growing the person rather than shrinking the problem. As ESRD is a predominantly medical problem, many of the papers I read while developing ideas for the research were in medical journals. Depression, although widely discussed in the ESRD literature, is often described in biomedical terms and I wonder if this primed me to think of depression in this way. This may have led me to approach the research in a way that was incompatible with the ACT model i.e. identifying individuals who fit into a diagnostic category and offering them an intervention to address the experiences that situate them in this category. I wonder how recruitment may have differed if patients had been offered the same intervention but told that it would help them to grow as an individual, do more of what is most important to them and improve their well-being. This would have been more compatible with the ACT model and may have been more appealing, although it is likely that a different group of individuals would be recruited.

Having previously perceived my research as a failed trial and questioned how I could have done things differently, my perception during the analysis and write-up changed once more. In all my pessimism about the failed opportunity, I had forgotten what I had set out to do. The objective of the trial was to determine the feasibility of a full trial examining an ACT self-help intervention for depression in ESRD. To that end, low recruitment numbers were no more a weakness than they were a strength. Frustrating though it had felt at times, I had achieved my research aims. This was not a failed trial.

I reflected on the ACT model and the research that I had drawn upon to justify its use to treat depression in ESRD. These studies had shown a relationship between avoidance and distress and this had been replicated in my research. ESRD patients who are depressed have a tendency towards avoidant coping. It seems plausible that these avoidant tendencies would extend to participation in my research. I was trying to recruit the very individuals who were most likely to avoid participating.

Overall, I feel satisfied with the project and it has broadened my awareness of the challenges of carrying out gold-standard research. It also expanded my understanding of the ACT model and gave me the confidence to use it in my clinical practice. I have since used ACT in individual therapeutic work with ESRD patients and found it to be a well-suited model for a group of patients who are faced with a lifelong, irreversible condition, and for whom acceptance of the disease and the associated pain, in the service of what is most important to them, may be the most meaningful outcome.

6. Extended References

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Appendices

Appendix A: Psychotherapy outcome study methodology rating scale

Item	Rating and description
i. Clarity of sample description	<p>0 = Vague description of sample (e.g. only mentioned whether patients were diagnosed with the disorder).</p> <p>1 = Fair description of sample (e.g. mentioned inclusion/exclusion criteria, demographics, etc.).</p> <p>2 = Good description of sample (e.g. mentioned inclusion/exclusion criteria, demographics, and the prevalence of comorbid disorders).</p>
ii. Severity/chronicity of the disorder	<p>0 = Severity/chronicity was not reported and/or sub-syndromal patients were included in the sample.</p> <p>1 = All patients met the criteria for the disorder. Sample includes acute (<1 year) and/or low severity.</p> <p>2 = Sample consisted entirely of chronic (>1 year) patients of at least moderate severity.</p>
iii. Representativeness of the sample	<p>0 = Sample is very different from patients seeking treatment for the disorder (e.g. there are excessively strict exclusion criteria).</p> <p>1 = Sample is somewhat representative of patients seeking treatment for the disorder (e.g. patients were only excluded if they met criteria for other major disorders).</p> <p>2 = Sample is very representative of patients seeking treatment for the disorder (e.g. authors made efforts to ensure representativeness of sample).</p>
iv. Reliability of the diagnosis in question	<p>0 = The diagnostic process was not reported, or not assessed with structured interviews by a trained interviewer.</p> <p>1 = The diagnosis was assessed with structured interview by a trained interviewer.</p> <p>2 = The diagnosis was assessed with structured interview by a trained interviewer and adequate inter-rater reliability was demonstrated (e.g. kappa coefficient).</p>
v. Specificity of outcome measures	<p>0 = Very broad outcome measures, not specific to the disorder (e.g. SCL-90R total score).</p> <p>1 = Moderately specific outcome measures.</p> <p>2 = Specific outcome measures, such as a measure for each symptom cluster.</p>
vi. Reliability and validity of outcome measures	<p>0 = Measures have unknown psychometric properties, or properties that fail to meet current standards of acceptability.</p> <p>1 = Some, but not all measures have known or adequate psychometric properties.</p> <p>2 = All measures have good psychometric properties. The outcome measures are the best available for the authors' purpose.</p>
vii. Use of blind evaluators	<p>0 = Blind assessor was not used (e.g. assessor was the therapist, assessor was not blind to treatment condition, or the authors do not specify).</p> <p>1 = Blind assessor was used, but no checks were used to assess the blind.</p> <p>2 = Blind assessor was used in correct fashion or measures completed online. Checks were used to assess whether the assessor was aware of treatment condition.</p>
viii. Assessor training	<p>0 = Assessor training and accuracy are not specified, or are unacceptable.</p> <p>1 = Minimum criterion for assessor training is specified (e.g. assessor has had specific training in the use of the outcome measure), but accuracy is not monitored or reported.</p> <p>2 = Minimum criterion of assessor training is specified. Inter-rater reliability was checked, and/or assessment procedures were calibrated during the study to prevent evaluator drift; n/a = if measures completed online.</p>
ix. Assignment to treatment	<p>0 = Biased assignment, e.g. patients selected their own therapy or were assigned in another non-random fashion, or there is only one group.</p> <p>1 = Random or stratified assignment. There may be some systematic bias but not enough to pose a serious threat to internal validity. There may be therapist by treatment confounds. N may be too small to protect against bias.</p> <p>2 = Random or stratified assignment, and patients are randomly assigned to therapists within condition. When theoretically different treatments are used, each treatment is provided by a large enough number of different therapists. N is large enough to protect against bias.</p>
x. Design	<p>0 = Active treatment vs. wait-list control, or briefly described TAU.</p> <p>1 = Active treatment vs. TAU with good description, or placebo condition.</p> <p>2 = Active treatment vs. another previously empirically documented active treatment.</p>

Continued.

Continued.

xi. Power analysis	<p>0 = Biased assignment, e.g. patients selected their own therapy or were assigned in another non-random fashion, or there is only one group.</p> <p>1 = Random or stratified assignment. There may be some systematic bias but not enough to pose a serious threat to internal validity. There may be therapist by treatment confounds. N may be too small to protect against bias.</p> <p>2 = Random or stratified assignment, and patients are randomly assigned to therapists within condition. When theoretically different treatments are used, each treatment is provided by a large enough number of different therapists. N is large enough to protect against bias.</p>
xii. Assessment points	<p>0 = Only pre- and post-treatment, or pre- and follow-up.</p> <p>1 = Pre-, post-, and follow-up <1 year.</p> <p>2 = Pre-, post-, and follow-up >1 year.</p>
xiii. Manualised, replicable, specific treatment programs	<p>0 = Description of treatment procedure is unclear, and treatment is not based on a publicly available, detailed treatment manual. Patients may be receiving multiple forms of treatment at once in an uncontrolled manner.</p> <p>1 = Treatment is not designed for the disorder, or description of the treatment is generally clear and based on a publicly available, detailed treatment manual, but there are some ambiguities about the procedure. Patients may have received additional forms of treatment, but this is balanced between groups or otherwise controlled.</p> <p>2 = Treatment is designed for the disorder. A detailed treatment manual is available, and/or treatment is explained in sufficient detail for replication. No ambiguities about the treatment procedure. Patients receive only the treatment in question.</p>
xiv. Number of therapists	<p>0 = Only one therapist, i.e. complete confounding between therapy and therapist.</p> <p>1 = At least two therapists, but the effect of therapist on outcome is not analysed.</p> <p>2 = Three, or more therapists, and the effect of therapist on outcome is analysed.</p>
xv. Therapist training/experience	<p>0 = Very limited clinical experience of the treatment and/or disorder (e.g. students).</p> <p>1 = Some clinical experience of the treatment and/or disorder.</p> <p>2 = Long clinical experience of the treatment and the disorder (e.g. practising therapists).</p>
xvi. Checks for treatment adherence	<p>0 = No checks were made to assure that the intervention was consistent with protocol.</p> <p>1 = Some checks were made (e.g. assessed a proportion of therapy tapes).</p> <p>2 = Frequent checks were made (e.g. weekly supervision of each session using a detailed rating form).</p>
xvii. Checks for therapist competence	<p>0 = No checks were made to assure that the intervention was delivered competently.</p> <p>1 = Some checks were made (e.g. assessed a proportion of therapy tapes).</p> <p>2 = Frequent checks were made (e.g. weekly supervision of each session using a detailed rating form).</p>
xviii. Control of concomitant treatments (e.g. medications)	<p>0 = No attempt to control for concomitant treatments, or no information about concomitant treatments provided. Patients may have been receiving other forms of treatment in addition to the study treatment.</p> <p>1 = Asked patients to keep medications stable and/or to discontinue other psychological therapies during the treatment.</p> <p>2 = Ensured that patients did not receive any other treatments (medical or psychological) during the study.</p>
xix. Handling of attrition	<p>0 = Proportions of attrition are not described, or described but no dropout analysis is performed.</p> <p>1 = Proportions of attrition are described, and dropout analysis or intent-to-treat analysis is performed.</p> <p>2 = No attrition, or proportions of attrition are described, dropout analysis is performed, and results are presented as intent-to-treat analysis.</p>
xx. Statistical analyses and presentation of results	<p>0 = Inadequate statistical methods are used and/or data are not fully presented.</p> <p>1 = Adequate statistical methods are used but data are not fully presented.</p> <p>2 = Adequate statistical methods are used and data are presented with M and SD.</p>
xxi. Clinical significance	<p>0 = No presentation of clinical significance was done.</p> <p>1 = An arbitrary criterion for clinical significance was used and the conditions were compared regarding percent clinically improved.</p> <p>2 = Jacobson's criteria for clinical significance were used and presented for a selection (or all) of the outcome measures, and conditions were compared regarding percent clinically improved.</p>

xxii. Equality of therapy hours (for non-wait-list designs only)

0 = Conditions differ markedly (>20% difference in therapy hours).
1 = Conditions differ somewhat (10–19% difference in therapy hours).
2 = Conditions do not differ (<10% difference in therapy hours).

Appendix B: National Research Ethics Committee approval letter

14/NW/1532

Page 1



NRES Committee North West - Preston

Barlow House
3rd Floor
4 Minshull Street
Manchester
M1 3DZ

Telephone: 0161 625 7818
Fax: 0161 625 7299

06 January 2015

Mr William Vogt
Trainee Clinical Psychologist
Lincolnshire Partnership NHS Foundation Trust
School of Psychology
Bridge House
University of Lincoln
LN6 7TS

Dear Mr Vogt

Study title:	Acceptance and Commitment Therapy self-help intervention for depression in haemodialysis patients: A feasibility randomised controlled trial
REC reference:	14/NW/1463
IRAS project ID:	156756

Thank you for responding to the Committee's request for further information on the above research and submitting revised documentation.

The further information has been considered on behalf of the Committee by the Chair.

We plan to publish your research summary wording for the above study on the HRA website, together with your contact details. Publication will be no earlier than three months from the date of this favourable opinion letter. The expectation is that this information will be published for all studies that receive an ethical opinion but should you wish to provide a substitute contact point, wish to make a request to defer, or require further information, please contact the REC Manager, Mrs Carol Ebenezer, nrescommittee.northwest-preston@nhs.net. Under very limited circumstances (e.g. for student research which has received an unfavourable opinion), it may be possible to grant an exemption to the publication of the study.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised, subject to the conditions specified below.

Conditions of the favourable opinion

The favourable opinion is subject to the following conditions being met prior to the start of the

study.

Management permission or approval must be obtained from each host organisation prior to the start of the study at the site concerned.

Management permission ("R&D approval") should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements.

Guidance on applying for NHS permission for research is available in the Integrated Research Application System or at <http://www.rdforum.nhs.uk>.

Where a NHS organisation's role in the study is limited to identifying and referring potential participants to research sites ("participant identification centre"), guidance should be sought from the R&D office on the information it requires to give permission for this activity.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

Sponsors are not required to notify the Committee of approvals from host organisations

Registration of Clinical Trials

All clinical trials (defined as the first four categories on the IRAS filter page) must be registered on a publically accessible database. This should be before the first participant is recruited but no later than 6 weeks after recruitment of the first participant.

There is no requirement to separately notify the REC but you should do so at the earliest opportunity e.g. when submitting an amendment. We will audit the registration details as part of the annual progress reporting process.

To ensure transparency in research, we strongly recommend that all research is registered but for non-clinical trials this is not currently mandatory.

If a sponsor wishes to request a deferral for study registration within the required timeframe, they should contact hra.studyregistration@nhs.net. The expectation is that all clinical trials will be registered, however, in exceptional circumstances non registration may be permissible with prior agreement from NRES. Guidance on where to register is provided on the HRA website.

It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

Ethical review of research sites

NHS sites

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

Non-NHS sites

The Committee has not yet completed any site-specific assessment (SSA) for the non-NHS research site(s) taking part in this study. The favourable opinion does not therefore apply to any non-NHS site at present. We will write to you again as soon as an SSA application(s) has been reviewed. In the meantime no study procedures should be initiated at non-NHS sites.

Approved documents

The final list of documents reviewed and approved by the Committee is as follows:

<i>Document</i>	<i>Version</i>	<i>Date</i>
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only)		
Letters of invitation to participant [Invitation Letter]	1.1	19 October 2014
Other [Summary CV for Nima Moghaddam]	1.0	10 October 2014
Other [Eligibility Checklist]	1.1	15 December 2014
Participant consent form [Consent Form]	1.3	15 December 2014
Participant information sheet (PIS) [Participant Information Sheet]	1.3	15 December 2014
REC Application Form [REC_Form_14112014]		14 November 2014
Research protocol or project proposal [Protocol]	1.1	17 August 2014
Response to Request for Further Information		
Summary CV for Chief Investigator (CI) [Summary CV for Chief Investigator (CI)]	1.0	11 November 2014
Summary CV for supervisor (student research) [Summary CV for Roshan das Nair]	1.0	01 July 2013
Validated questionnaire [Questionnaires]	1.0	12 September 2014

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

After ethical review

Reporting requirements

The attached document "*After ethical review – guidance for researchers*" gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study

The HRA website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

User Feedback

The Health Research Authority is continually striving to provide a high quality service to all applicants and sponsors. You are invited to give your view of the service you have received and the application procedure. If you wish to make your views known please use the feedback form available on the HRA website: <http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance/>

HRA Training

We are pleased to welcome researchers and R&D staff at our training days – see details at <http://www.hra.nhs.uk/hra-training/>

14/NW/1463	Please quote this number on all correspondence
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With the Committee's best wishes for the success of this project.

Yours sincerely



Dr Patricia Wilkinson
Chair

Email: nrescommittee.northwest-preston@nhs.net

Enclosures: "After ethical review – guidance for
researchers"

Copy to: Professor Sara Owen
Charlotte Davies, Nottingham University Hospitals NHS Trust

Appendix C: Local Research and Innovation Department approval letter



Nottingham University Hospitals **NHS**
NHS Trust

3rd March 2015

Research & Innovation
Nottingham Health Science Partners
C Floor, South Block
Queen's Medical Centre Campus
Derby Road, Nottingham NG7 2UH

Tel: 0115 9709049
www.nuhrise.org

Dr Emma Coyne
Dialysis Unit
City Hospital Campus
Nottingham University Hospitals NHS Trust
Hucknall Road
Nottingham
NG5 1PB

Dear Dr Emma Coyne

Short Title / Acronym	Feasibility RCT of ACT selfhelp for depression in haemodialysis /
CSP Number	
R&I REF	15CP001
Long Title	Acceptance and Commitment Therapy selfhelp intervention for depression in haemodialysis patients: A feasibility randomised controlled trial
PROJECT MILESTONES	
Recruitment Target	30
Date of Valid Submission	02/03/2015
Recruitment End Date	29/02/2016
1st Patient to be Recruited by	11/05/2015

The R&I Department has reviewed the following documents and NHS permission for the above research has been granted on the basis described in the application form, protocol, and supporting documentation. The documents reviewed were:

TAFR00905_NUH Approval Letter_Version 1.1
Effective Date: 12/12/2014

We are here for you

Document	Version	Date
Letters of invitation to participant	1.1	19 Oct 2014
Participant consent form	1.3	15 Dec 2014
Participant Information Sheet	1.3	15 Dec 2014
Research protocol	1.1	17 Aug 2014
Validated questionnaire	1.0	12 Sep 2014
Eligibility checklist	1.1	15 Dec 2014

Your study now has NHS permission, on the understanding and provision that you will follow the conditions set out below.

Conditions of Approval

The Principal Investigator is responsible for:

1. Compliance with all relevant laws, regulations and codes of practice applicable to the trial including but not limited to, the UK Clinical Trials Regulations, Medicines for Human Use (Clinical Trial) Regulations 2004, principles of Good Clinical Practice, the World Medical Association Declaration of Helsinki entitled 'Ethical Principles for Medical Research Involving Human Subjects' (2013 version), the Human Rights Act 1998, the Data Protection Act 1998, the Medicines Act 1968, and the NHS Research Governance Framework for Health and Social Care (version 2 April 2005). Should any of these be revised and reissued this will apply. Copies of the up-to-date regulations are available from the R&I Office or via the R&I website <http://nuhrise.org>.
2. Submission of study amendments to the Ethics committee and MHRA in accordance with the IRAS guidelines. Amendments and information with regards to changes in study status must be sent to R&I, (this includes changes to the local study team). Within 35 days from the receipt of a valid amendment submission, the R&I department will inform you if the amendment cannot be implemented locally. If no objections are raised NHS permission is valid and the amendment may be implemented.

When submitting documents for studies adopted into the NIHR portfolio please send the information to the Clinical Research Network: East Midlands (CRN:EM) (CSP.CRNEastMidlands@NIHR.ac.uk). When submitting documents for all other studies please use the email address rdamend@nuh.nhs.uk.

3. Ensuring all study personnel, not employed by the Nottingham University Hospitals NHS Trust hold either honorary contracts/letters of access with this Trust, before they have access to any patients or staff, their data, tissue or organs or any NUH facilities.

4. For initiating and delivering research in accordance with the Department of Health's Plan for Growth. The first patient, first visit should occur within 70 days from the receipt of a valid submission in R&I. This applies to all studies where :
 - i. The research is classed as a "clinical trial" on the IRAS filter page (first 4 categories)
5. Ensuring the research team via an identified individual, collaborates with the department of R&I and the CRN:EM in reporting recruitment data using Documas and the CRN EM Study Tracker.
6. Ensuring that for GTAC-approved studies, the NHS permission is forwarded to GTAC via the sponsor. GTAC should then issue a site authorisation letter which must be received by each site prior to recruitment commencing. A copy of this letter must be forwarded to R&I.
7. Comply with requests from NUH R&I to allow monitoring of research to comply with the Research Governance Framework and other applicable regulations.
8. Record all types of adverse events (including Suspected Unexpected Serious Adverse Drug Reaction - SUSARS) in the patient medical records and study documentation and report to the sponsor as required by the protocol.
9. Report any Serious Breach of the UK Clinical Trial regulations in connection with the trial or Serious Breach of the protocol, immediately after becoming aware of the breach to the study sponsor.
10. Reporting any changes to the study to R&I by letter or e mail. These should not be implemented until agreed with R&I.

For NUH sponsored studies only, the Chief Investigator is responsible for:

- i. All duties as detailed in the "Clinical Trial Delegation of Sponsorship responsibilities to Chief Investigator" agreement.
- ii. Contacting the sponsor for review of all amendment documentation prior to submission to the HRA and MHRA. Please note that according to HRA and MHRA regulations, all submissions of amendments need to be signed by the authorised sponsor's representative. All relevant documentation should be emailed to rdamend@nuh.nhs.uk.
- iii. Sending copies of the completed Annual Progress Reports, Development Safety Update Reports, and End of Study report required by the Ethics Committee and the MHRA (if appropriate) to the sponsor researchsponsor@nuh.nhs.uk.
- iv. Notifying NUH R&I of all SAEs by completing and sending the "Serious Adverse Event reporting form" to R&I (only via fax, e-mail or by hand), within 24hrs of becoming aware of the event. Further guidance can be found in the R&I Adverse Event SOP (SOP-RES-019).
- v. Reporting any Serious Breach of the UK Clinical Trial regulations in connection with the trial or Serious Breach of the protocol, immediately after becoming aware of the breach to NUH R&I as sponsor. Fur-

ther guidance can be found in the R&I Non Compliance and Serious Breach Reporting SOP (SOP-RES-017).

This approval letter constitutes a favourable Site Specific Assessment (SSA) for this site.

If you have any queries regarding the milestones or points detailed in this letter, please contact the Research Project Manager responsible for managing the performance of the study at NUH. This information is available on <http://nuhrise.org>.

Please note that the R&I department maintains a database containing study related information, and personal information about individual investigators e.g. name, address, contact details etc. This information will be managed according to the principles established in the Data Protection Act.

Yours sincerely,



Dr Brian Thomson / Dr Maria Koufali
Director of Research and Innovation / Deputy Director Research and Innovation

Appendix D: National Research Ethics Committee substantial amendment approval letter

Page 1



NRES Committee North West - Preston

Barlow House
3rd Floor
4 Minshull Street
Manchester
M1 3DZ

Tel: 0161 625 7818
Fax: 0161 625 7299

31 July 2015

Mr William Vogt
Trainee Clinical Psychologist
Lincolnshire Partnership NHS Foundation Trust
School of Psychology
Bridge House
University of Lincoln
LN6 7TS

Dear Mr Vogt

Study title:	Acceptance and Commitment Therapy self-help intervention for depression in haemodialysis patients: A feasibility randomised controlled trial
REC reference:	14/NW/1463
Amendment number:	1
Amendment date:	27 July 2015
IRAS project ID:	156756

Additional questionnaires for screening process.

The above amendment was reviewed by the Sub-Committee in correspondence.

Ethical opinion

The members of the Committee taking part in the review gave a favourable ethical opinion of the amendment on the basis described in the notice of amendment form and supporting documentation.

The members had no ethical issues with this amendment but requested a revised Participant Information Sheet to include the timings for the questionnaires. This was provided.

Approved documents

The documents reviewed and approved at the meeting were:

Document	Version	Date
Notice of Substantial Amendment (non-CTIMP)	1	27 July 2015
Other [screening questionnaires]	1	20 July 2015
Participant information sheet (PIS)	1.4	31 July 2015
Research protocol or project proposal	1.3	20 July 2015

Membership of the Committee

The members of the Committee who took part in the review are listed on the attached sheet.

R&D approval

All investigators and research collaborators in the NHS should notify the R&D office for the relevant NHS care organisation of this amendment and check whether it affects R&D approval of the research.

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

We are pleased to welcome researchers and R & D staff at our NRES committee members' training days – see details at <http://www.hra.nhs.uk/hra-training/>

14/NW/1463:	Please quote this number on all correspondence
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Yours sincerely



Dr Patricia Wilkinson
Chair

E-mail: nrescommittee.northwest-preston@nhs.net

Enclosures: *List of names and professions of members who took part in the review*

Copy to: *Charlotte Davies, Nottingham University Hospitals NHS Trust
Professor Sara Owen*

NRES Committee North West - Preston

Attendance at Sub-Committee of the REC meeting on 31 July 2015

Committee Members:

<i>Name</i>	<i>Profession</i>	<i>Present</i>	<i>Notes</i>
Dr Rob Monks	Senior Lecturer Department of Nursing	Yes	
Dr Patricia Wilkinson	General Practitioner/ Chair	Yes	

Also in attendance:

<i>Name</i>	<i>Position (or reason for attending)</i>
Mrs Carol Ebenezer	REC Manager

Appendix E: Local Research and Innovation Department substantial amendment approval letter

Nottingham University Hospitals 
NHS Trust



21st September 2015

Dr Emma Coyne
Dialysis Unit
City Hospital Campus
Nottingham University Hospitals NHS Trust
Hucknall Road
Nottingham
NG5 1PB

Research & Innovation
Nottingham Health Science Partners
C Floor, South Block
Queen's Medical Centre Campus
Derby Road, Nottingham NG7 2UH
Direct Dial: 0115 849 3320
R&I Dept: 0115 970 9049
Tel: 0115 924 9924
Fax: 0115 849 3295
www.nuh.nhs.uk
nuhrise.org

Dear Dr Emma Coyne

Short Title / Acronym	Feasibility RCT of ACT selfhelp for depression in haemodialysis /
CSP Number	
R&I REF	15CP001
Long Title	Acceptance and Commitment Therapy selfhelp intervention for depression in haemodialysis patients: A feasibility randomised controlled trial
PROJECT MILESTONES	
Recruitment Target	30
Date of Valid Submission	02/03/2015
Recruitment End Date	29/02/2016

The R&I Department have considered the following documents submitted on 31/07/15 and there is no objection from the NUH R&I Office to the implementation of this amendment. The documents reviewed are detailed below:

Document	Version	Date
Screening Questionnaire	1	20 July 2015
Participant Information Sheet	1.4	31 July 2015
Protocol	1.3	20 July 2015
REC Approval		31 July 2015

We are here for you

The amendment may therefore be implemented immediately at this site under the conditions of the existing NHS Permission.

Please note that you may only implement changes that were described in the documents listed above.

Yours sincerely,



Dr Brian Thomson / Dr Maria Koufali
Director of R&D / Deputy Director Research and Innovation

We are here for you

Appendix F: Participant Information Sheet

(Final version 1.4: 31/07/15)

Title of study: Acceptance and Commitment Therapy self-help intervention for depression in haemodialysis patients: A feasibility randomised controlled trial

Researchers: William Vogt (Chief Investigator), Dr Roshan das Nair, Dr Nima Moghaddam, Dr Emma Coyne

Sponsor: Professor Sara Owen, University of Lincoln

We would like to invite you to take part in our research study. Before you decide we would like you to understand why the research is being done and what it would involve for you. One of our team will go through the information sheet with you and answer any questions you have. Talk to others about the study if you wish. Ask us if there is anything that is not clear.

What is the purpose of the study?

Depression is experienced by 20-40% of people with End-Stage Renal Disease (ESRD). Depression not only affects the quality of life of individuals with ESRD but is also associated with higher rates of hospitalisation and worse physical health outcomes.

Acceptance and Commitment Therapy (ACT) is a talking therapy that has been found to be an effective treatment for depression and has been used successfully as a self-help treatment for other chronic physical health problems. However, no study has examined the effectiveness of an ACT self-help treatment for depression in ESRD. We want to know whether it is feasible to conduct such a study and will look at the suitability of our recruitment, assessment methods and our self-help treatment, and help us to calculate the number of people we will need for a larger study.

Do I have to take part?

It is up to you to decide whether you wish to join the study. If you decide to take part you are still free to withdraw at any time and without giving a reason. This will not affect your legal rights or your medical care.

Can anyone take part?

Only people who have been receiving haemodialysis for more than 3 months and are experiencing symptoms of depression can take part.

What will happen to me if I take part?

If you are willing to take part, you will be asked to complete some questionnaires which will include some questions about your mood. This will take approximately 10 minutes.

If the questionnaires suggest that you are experiencing some distress you will be eligible to take part. If your scores do not indicate that you have depression, you will not be eligible to take part.

If you agree to take part, you will be asked to fill in some further questionnaires.

After these assessments you will be put into one of two groups. Which group you are allocated to will be determined purely by chance (randomly). This is the fairest way to ensure that each person has an equal chance of being in either group.

Group 1

Group 1 will be given an ACT self-help workbook. This book contains information about ACT as well as some exercises to help develop your skills. This group will be required to complete several chapters of the workbook every week for six weeks and will continue to receive their usual care. Participants will be given information about which chapters to complete each week. Our researcher will provide up to 30 minutes per week of telephone support to help complete the chapters. An appropriate time for these phone calls will be agreed with each participant.

Once participants have completed the self-help workbook, they will be asked to fill in some of the questionnaires again. About two months later they will be asked to complete the questionnaires for a final time. It will take about 20 minutes to complete the questionnaires each time.

Group 2

Group 2 will **not** receive the ACT self-help workbook but will continue to receive their usual care. As with group 1, participants in group 2 will be asked to complete the questionnaires twice more, about 2 and 4 months after being allocated to the group.

Some participants from both groups will be invited to give feedback interviews to find out about their experience of being involved in our study.

Will everyone who wants to take part in the feedback interviews be interviewed?

There is an option on the consent form to state whether or not you want to take part in the interviews. Not everyone who wants to take part in these interviews will be selected. Who takes part in the feedback interviews will be determined purely by chance (randomly). This is the fairest way to ensure that each person has an equal chance of being interviewed. Anyone who does not want to take part in these interviews does not have to do so.

Please be assured that taking part in this study, whichever group you are allocated to, will not influence or delay your normal medical care.

Continued

Expenses and payments

Participants will not be paid to participate in the study. Travel expenses will be offered for any visits incurred as a result of participation.

What are the possible disadvantages and risks of taking part?

We appreciate that taking part will use your time and may therefore be inconvenient. If you are put into the self-help group, you may talk about your problems during telephone conversations with our researcher. Talking about your problems can occasionally be upsetting, but our researcher is trained to help make you feel as comfortable as possible. The interview and any other aspect of your involvement can stop at any time if you do not wish to continue. However, if during the interview or telephone conversations you disclose something that raises serious concerns about your safety or the safety of others, we may be obliged to break confidentiality and contact your GP and/or refer you to the Clinical Psychologist within the renal service. You will be told if confidentiality is going to be broken.

What are the possible benefits of taking part?

Taking part in our study means that you may possibly help people with ESRD in the future. The information we get from this study will help us decide whether we should develop this approach further.

What happens when the research study stops?

When the research stops your usual care will continue.

What if there is a problem?

If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions. The researcher's contact details are given at the end of this information sheet. If you remain unhappy and wish to complain formally you can do this by contacting NHS Complaints. Details can be obtained from your hospital.

Will my taking part in the study be kept confidential?

We will follow ethical and good practice procedures and all information about you will be handled in complete confidence. All information which is collected about you during the research will be kept **strictly confidential**, stored in a secure and locked office, and on a password protected database.

Your personal data (address, telephone number) will be kept for a year after the end of the study so that we are able to contact you about the findings of the study and possible follow-up studies, unless you tell us that you do not wish to be contacted. All other research data will be kept securely for 7 years. After this time your data will be disposed of securely. During this time all precautions will be taken to maintain your

confidentiality. Only members of the research team will have access to your personal data.

What will happen if I don't want to carry on with the study?

Your participation is voluntary and you are free to withdraw at any time, without giving any reason, and without your legal rights or medical care being affected. If you withdraw then the information collected so far cannot be erased and this information may still be used in the project analysis.

Involvement of the General Practitioner/Family doctor (GP)

If you take part in this study, we will write to your GP to notify them of your participation in the research. We will explain in the letter that our questionnaire indicates that you may be experiencing symptoms of depression. If at any point during the study, there are serious concerns regarding your safety we will contact your GP again.

What will happen to the results of the research study?

The information from this study will help us establish the value of this treatment for people receiving haemodialysis. The results of the study may be presented to other researchers, at meetings and through publication in scientific journals. Although these reports may include direct quotes of what you have said, we will ensure that it will not be possible for anyone to identify you from them. If you ask the researcher, we would be happy to send you a copy of the results when they are available.

Who is organising and funding the research?

This research is being organised and funded by the University of Lincoln.

Who has reviewed the study?

All research in the NHS is looked at by independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given favourable opinion by NRES Committee North West – Preston.

Contact details

If you have any further questions about this study, or wish to contact the study sponsors, please contact our researcher

Name of researcher: William Vogt

Address: School of Psychology (DClinPsy), University of Lincoln, Brayford Pool, Lincoln LN6 7TS

Telephone: 07525 219 365

Email: 13451711@students.lincoln.ac.uk

You can also contact the University of Lincoln School of Psychology Ethics Committee

Telephone: 01522 88 6180

Email: soprec@lincoln.ac.uk

Address: as above

Complaints

If you have any complaints about this study, please contact the University of Lincoln School of Psychology Research Ethics Committee on the contact details above or Nottingham University Hospitals NHS Trust Patient Advice and Liaison Service (PALS)

Address:

Patient Advice and Liaison Service
Nottingham City Hospital
Hucknall Rd
Nottingham
NG5 1PB

Freephone: 0800 18 30 204

Email: PALS@nuh.nhs.uk

Thank you for taking the time to read this invitation

Appendix G: Consent Form

(Final version 1.3: 15/12/14)

Title of study: Acceptance and Commitment Therapy self-help intervention for depression in haemodialysis patients: A feasibility randomised controlled trial (Self-help for haemodialysis patients with depression)

REC ref: 14/NW/1463

Name of Researcher: William Vogt

Name of Participant:

1. I confirm that I have read and understand the information sheet version numberdated..... for the above study and have had the opportunity to ask questions. ☐
2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, and without my medical care or legal rights being affected. I understand that should I withdraw then the information collected so far cannot be erased and that this information may still be used in the project analysis. ☐
3. I understand that relevant sections of my medical notes and data collected in the study may be looked at by authorised individuals from the University of Lincoln, the research group and regulatory authorities where it is relevant to my taking part in this study. I give permission for these individuals to have access to these records and to collect, store, analyse and publish information obtained from my participation in this study. I understand that my personal details will be kept confidential. ☐
4. I would like to be contacted for an interview at a later stage of the study. ☐
5. I understand that any telephone conversations or interviews which take place as part of the study may be recorded. ☐
6. I understand that if I take part in the interview, anonymised quotes from the interview and phone conversations may be used in publications that arise from this study ☐
7. I agree to my GP being informed of my participation in this study. ☐
8. I agree to take part in the above study. ☐

_____ Name of Participant	_____ Date	_____ Signature
------------------------------	---------------	--------------------

_____ Name of Person taking consent (if different from Chief Investigator)	_____ Date	_____ Signature
--	---------------	--------------------

_____ Name of Chief Investigator	_____ Date	_____ Signature
-------------------------------------	---------------	--------------------

3 copies: 1 for participant, 1 for the project notes and 1 for the medical notes

Appendix H: Interview Schedule

Questions for all interviewees:

1. How did you find the recruitment process? What was it like be recruited at the dialysis unit? Did you find it intrusive? Was the information that you were given clear?
2. After signing up for the study, you were randomly allocated to the group who received the self-help book / to the group who didn't receive the self-help book. How did you find the allocation procedure? Did you understand this well? Did you think it was a fair way of allocating people to groups? If not, what would be a better way?
3. How did you find completing the questionnaires? Were the questions clear? Did they capture the right information? Were you happy with how long they took to complete?
4. Since been diagnosed with chronic kidney disease, have you ever received any psychological treatment? When was this? How long was this for? (e.g. number of sessions and length in time). What type of psychological treatment? What was the treatment for?
5. Since your diagnosis, have you ever been prescribed any medication for depression? When was this? How long was this for? What medication?
6. Have you read any other self-help books? What were they? What aspects of them were helpful?
7. Have you been to any mindfulness, meditation or therapeutic groups?
8. Have there been any significant changes to your medical care since taking part in the study? (e.g. kidney transplant, change to home haemodialysis).
9. What changes to the study (if any) would you recommend? You might want to think about the recruitment process, the intervention length or intensity, the telephone call length, intensity or regularity, the questionnaires. This could be something you have mentioned before or something new, it should help with future research.

Questions for intervention group only:

11. What did you think of the self-help manual? You might want to think about the style, content, language, length and interactivity.
12. What aspects of the intervention (self-help manual with telephone support) do you think might be difficult for people who receive dialysis?
13. What would make this treatment more appropriate or helpful for people who receive dialysis? (e.g. different format, length, more support)
14. Which aspects of the manual did you find most helpful?
15. Which aspects of the manual did you find least helpful?

16. Where did you usually read the book? (e.g. while on dialysis, at home)
17. What barriers made it difficult to read the book or complete the exercises? (e.g. life events, living situation, health)
18. Do you have any thoughts about self-help provided in a different format (e.g. computerised, audio)?
19. Do you think other dialysis patients would benefit from a self-help treatment with telephone support? Why?
20. What did you think of the telephone support? (e.g. length, regularity, intensity)

7. Poster

Acceptance & Commitment Therapy Self-Help for Depression in Haemodialysis: A Feasibility Randomised Controlled Trial

Will Vogt¹ Roshan das Nair¹, Nima G Moghaddam¹, Barnaby Proctor¹, Emma Coyne²
¹Trent Doctorate in Clinical Psychology; ²Renal Unit, Nottingham University Hospitals NHS Trust

Introduction

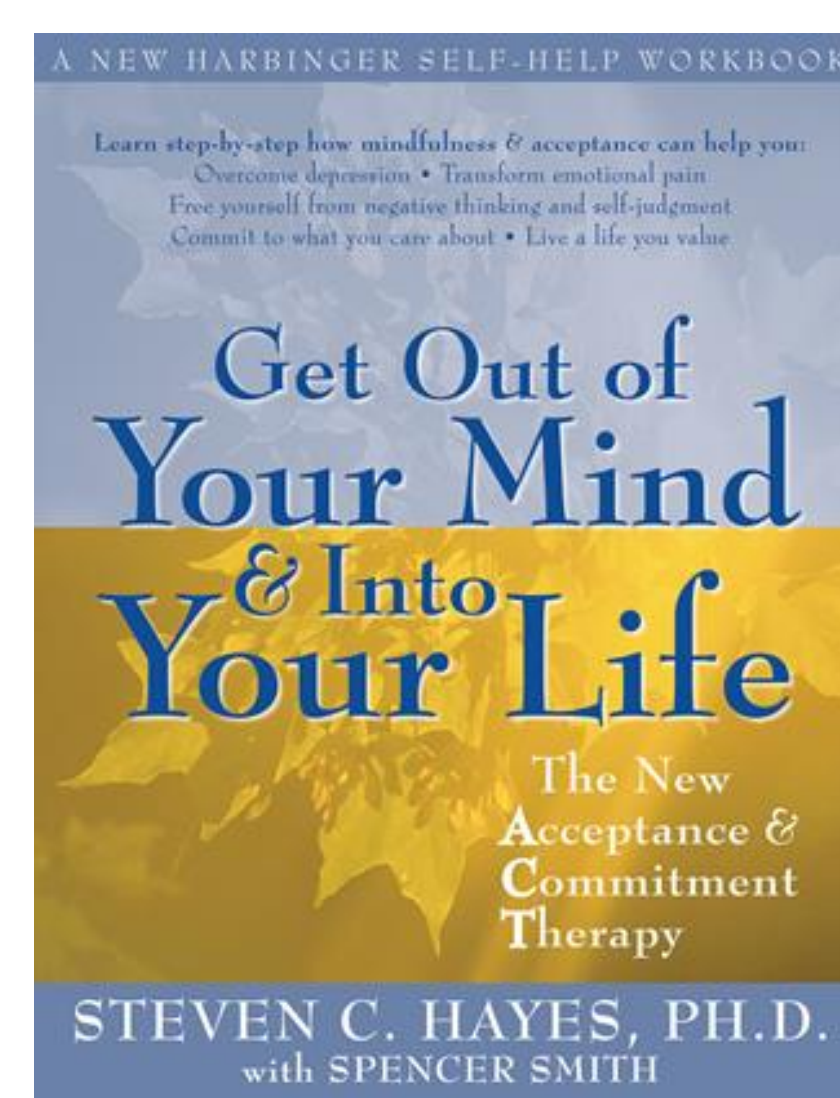
People with end-stage renal disease (ESRD) experience rates of depression ranging from 20 to 40%¹. Depression is associated with a range of negative health-related outcomes² and may be related to avoidant coping behaviours including behavioural disengagement³ and the suppression of negative emotions⁴.

Acceptance and Commitment Therapy (ACT) centres on interventions aimed at reducing experiential avoidance, encouraging acceptance as a means of fostering value-guided action⁵.

It has shown promising results in a number of long-term conditions⁶ and has been translated into a variety of self-help formats. ACT has never been tested as a treatment for depression in ESRD.

Research Aims

- To assess the feasibility of a full trial of a telephone-supported self-help intervention based on ACT.
- To generate data about the potential efficacy of the intervention by conducting individual level analysis.
- To examine the relationship between psychological flexibility and distress.



Participants were given a copy of **Get Out of Your Mind and Into Your Life**¹¹ - a general self-help text based on ACT.

Method

Participants were recruited from four outpatient haemodialysis units across Nottinghamshire, UK. The Patient Health Questionnaire⁷ (PHQ-9), EuroQol⁸ (EQ-5D-5L) health-related quality of life measure, Acceptance and Action Questionnaire II⁹ (AAQ-II) and Valued Living Questionnaire¹⁰ (VLQ) were completed at baseline and 2- and 4-months post-randomisation.

Participants in the intervention arm were asked to complete an ACT self-help manual over six weeks with weekly telephone support. Following completion of the trial, six participants were interviewed to examine the acceptability of the trial procedure and intervention. Interview data was analysed using framework analysis. Leeds Reliable Change Indicator was used to conduct individual level analysis.

Results

In total, 99 (36.87%) of 276 screening questionnaires were returned. Of these, 30 (30.3%) met the cut-off for depression on the PHQ-9 with nine enrolling in the trial.

AAQ-II scores of screened participants were positively associated with scores on the PHQ-9 indicating a positive relationship between psychological inflexibility and depression.

Interview data indicated that the recruitment process, randomisation procedure, and assessment methods were acceptable.

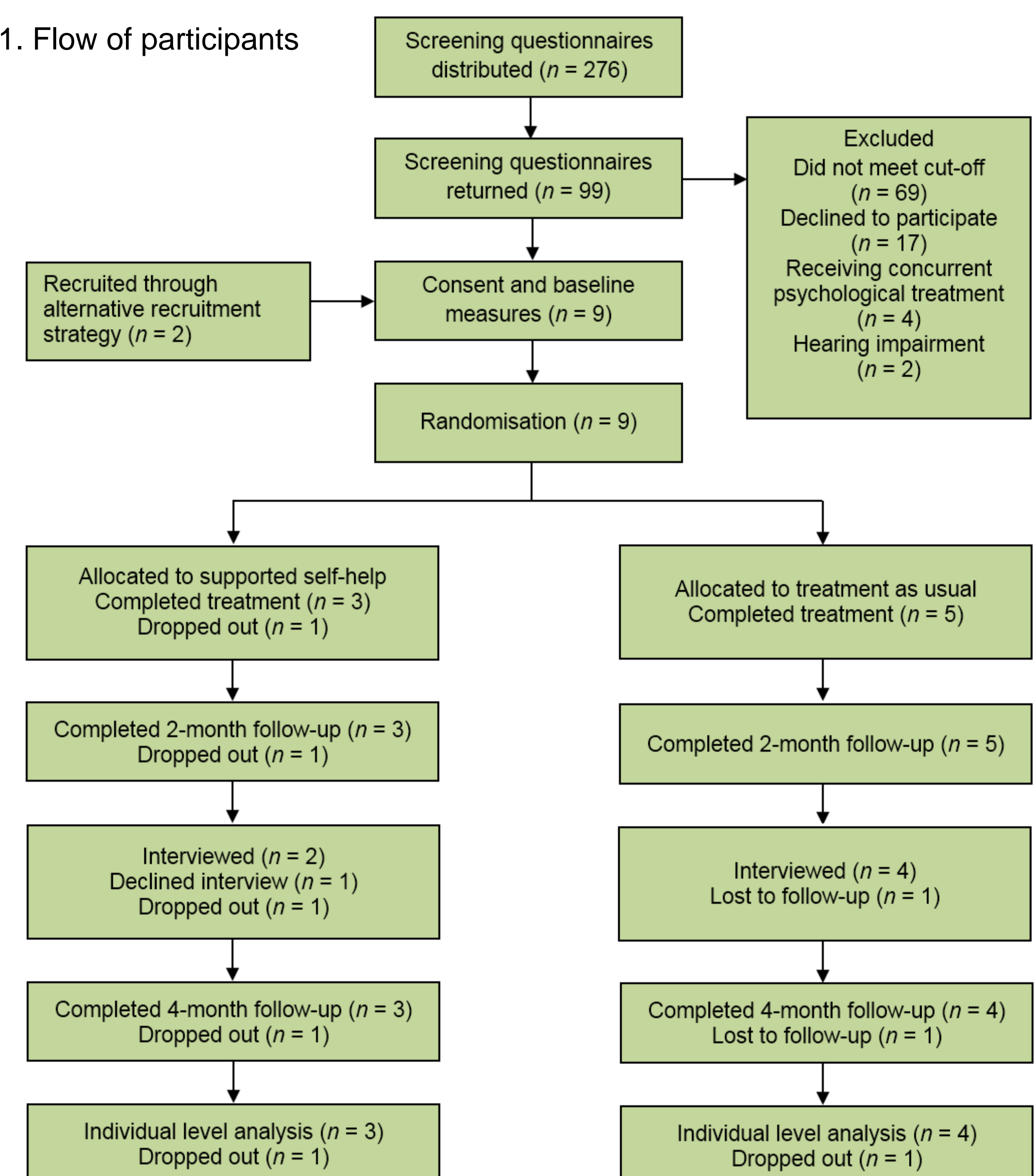
Only one in four of the participants in the ACT arm of the trial completed all chapters of the book with health problems the main barrier to completion. Individual level analysis revealed that one participant in each condition experienced clinically significant change in PHQ-9 scores.

Conclusion

Our findings indicate that a definitive trial examining the effectiveness of a telephone-supported ACT self-help intervention would not be feasible. Many aspects of the trial were acceptable to participants, including the main recruitment strategy, randomisation procedure and data collection methods. However, low recruitment numbers and poor adherence to the self-help manual indicate that a full-scale trial would not be viable.

Health problems may make it difficult for ESRD patients to engage in, and commit to, self-help interventions. Given the relationship between psychological flexibility and distress in ESRD, ACT interventions may have a utility. Research is needed to identify how best to approach ACT interventions with this population.

Figure 1. Flow of participants



Quotes

"I struggled to catch up with the book. I had a stroke two years ago so I'm a bit slower reading. I don't tend to read much."

"I'd been waiting for a parathyroidectomy for a while and then the op came up, so I tried getting to read it, but I couldn't, I couldn't concentrate."

"A lot of people... wouldn't want to do the self-help book, and there's also a lot that probably wouldn't want the phone calls either."